





## **Mandatory Continuing Education**

- The Proposed Bill

## **Drug Product Problem Report**

## A Survey of Pharmacy Cost Data in Maryland

- Bruce L. Myers, L. Darrell Stouffer, and Jacob W. Miller



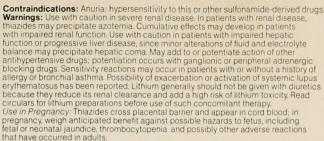
## yours...

We think there's a lot in common between your experience and ours. It's not easy to come by ... and it's not easy to replace. The training you went through, the service you've given, knowing the nature of the medications you dispense—these are important factors in your experience.



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that have occurred in adults.

Nursing Mothers: Thiazides appear in breast milk; if use of drug is deemed essential, patient should stop nursing.

Precautions: Perform periodic determination of serum electrolytes to detect possi-

Precautions: Perform periodic determination of serum electrolytes to detect possible electrolyte imbalance. Observe all patients for clinical signs of fluid or electrolyte imbalance, namely, hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs, irrespective of cause, are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting. Hypokalemia may develop, especially with brisk diuresis, in severe cirrhosis, with concomitant corticosteroid or ACTH therapy, or with inadequate oral electrolyte intake. Hypokalemia can sensitize or exaggerate response of heart to toxic effects of digitalis (e.g., increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements, such as foods with a high potassium content. Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare in the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients. Insulin requirements in diabetic patients may be increased, decreased, or unchanged, latent diabetes mellitus may become manifest. Thiazides may increase responsiveness to tubocurarine. Antihypertensive effects of the drug may be enhanced in postsympathectomy patients. May decrease arterial responsiveness to norepinephrine; this diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use. If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. Pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged therapy; thiazides should be discontinued before testing for parathyroid function.

Adverse Reactions: Gastrointestinal System—Anorexia; gastric irritation; nausea; vomiting; cramping; diarrhea; constipation; jaundice (intrahepatic cholestatic jaundice); pancreatitis; sialadentits.

cholestatic jaundice); pancreatitis; sialadenitis.

Central Nervous System—Dizziness; vertigo; paresthesias; headache; xanthopsia.

Hematologic—Leukopenia; agranulocytosis; thrombocytopenia; aplastic anemia.

Cardiovascular—Orthostatic hypotension (may be aggravated by alcohol, barbiturates or narcotics).

Hypersensitivity—Purpura; photosensitivity; rash; urticaria; necrotizing angiitis (vasculitis) (cutaneous vasculitis); fever; respiratory distress including pneumonitis; anaphylactic reactions.

Other—Hyperglycemia; glycosuria; hyperuricemia; muscle spasm; weakness; restlessness; transient blurred vision.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

Note: When used with other antihypertensive drugs, careful observations for changes in blood pressure must be made, especially during initial therapy. Dosage of other antihypertensive agents must be reduced by at least 50 percent as soon as this drug is added to the regimen. As blood pressure falls under the potentiating effect of this agent, further reduction in dosage, or even discontinuation, of other antihypertensive drugs may be necessary.

How Supplied: Tablets containing 25 mg hydrochlorothiazide each in bottles of 100 and 1000 and single-unit packages of 100; Tablets containing 50 mg hydrochlorothiazide each in bottles of 100, 1000, and 5000 and single-unit packages of 100; Tablets containing 100 mg hydrochlorothiazide each in bottles of 100. For more detailed information, consult your MSD representative or see full prescribing information. Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, Pa. 19486

#### In hypertension

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#### THE MARYLAND PHARMACIST

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### Drug Product Selection — The real significance

As the new responsibility of drug product selection falls upon the profession, we are faced with unique opportunities and challenges.

The first opportunity is to meet with the patient and discuss the drug selection process. This gives the pharmacist an opportunity to display that hard-earned knowledge and to improve the image of the profession.

Drug product selection will allow us greater discussion with the physician member of the health care team in explaining the brand of drug which is likely to be dispensed and the reasons for this choice. Our interprofessional relations should be enhanced.

This new opportunity will allow us to communicate with legislative representatives and the media to explain the professional and economic reasons for assuming this expanded role.

Finally, the new law will mean that we will have an increased professional dialogue with representatives of the drug manufacturers. I am certain that the flow of information regarding the drugs we dispense will only increase now that pharmacists can and will exercise their professional judgement in the selection process.

It sounds like an awful lot of work and responsibility . . . and it is! But it also happens to be the best way for us to expand our role as legitimate health care providers in the rapidly developing future ahead. It will be up to each of us to prove to ourselves and our patients that we are up to this challenge and equal to these opportunities.

Silar Doal

JANUARY, 1978 7

# Mandatory Continuing Education — The Proposed Bill

The Maryland Pharmaceutical Association's House of Delegates has adopted policy statements favoring the implementation of mandatory continuing education for pharmacists.

After several years of effort, the Association will again be supporting a legislative attempt to enact such a bill. At a recent meeting, the Board of Trustees of the Association adopted, in principle, a draft of a continuing education bill which was submitted by the M.Ph.A.'s Continuing Education Committee. Subsequent to that, a joint meeting of the Continuing Education and Legislative Committees of the Association met to finalize the language of the bill which is intended to be introduced in the Maryland General Assembly during the current session (1978).

The bill has been reviewed by members of the Board of Pharmacy, the Maryland Society of Hospital Pharmacists, the faculty of the University of Maryland School of Pharmacy, as well as a wide variety of pharmacists. It will be considered at the next meeting of the Maryland Tripartite Pharmacy Committee at its January meeting.

#### Nationwide Trend

Maryland will be joining a number of other states in what has become a nationwide trend in enacting continuing education laws. Sixteen states currently require that pharmacists earn professional continuing education credits as a condition for relicensure. Five more states have granted legislative authority to their boards of Pharmacy to promulgate regulations on the subject, and eleven more states have reported that they are in the process of some sort of activity leading to mandatory continuing education.

#### The Need For C.E.

For many years pharmacists have recognized the need for some method of assuring continuing competency within the profession beyond the initial degree and Board licensure. A pharmacist's knowledge can be outdated within five years of graduation and most pharmacists recognize that learning does not stop with graduation but is a life-long process. Professional competency is a moral responsibility on the part of all health care practitioners. The recent trends in medical malpractice liability only underscores this point.

Pharmacists are in the process of modifying their professional practice within the framework of the traditional structure of health care delivery. The very nature of our health care system is undergoing transformation which will alter the role that pharmacists will play in that structure. Continuing education is needed to keep in touch with these rapid changes in the practice of pharmacy.

Pharmacy's relationship with the health care consumer, and other health care providers will be enhanced through this tangible display of professional pride and initiative.

In its meeting with representatives from the HEW on the subject of National Health Insurance (see November, 1977 issue of the *Maryland Pharmacist*, page 34), the M.Ph.A. learned that HEW is concerned with the topic of continuing competency of health care providers as a prerequisite for participation in any eventual National Health Insurance program. The M.Ph.A. believes that control of mandatory C.E. must rest on a state level rather than in the hands of a federal bureaucracy.

#### Important Features of the Bill

The continuing education bill is not intended to work a hardship on any Maryland Pharmacist regardless of geographical location or specialty of practice. A variety of continuing education opportunities must be available and easily accessible to each pharmacist. The bill contains a list of those kinds of programs which could receive continuing education credit, a list of the possible program vehicles (such as cassette or correspondence programs) and a list of possible program sponsors.

The individual pharmacist has the responsibility for acquiring 30 hours (3.0 CEU's) in a biennium and maintaining all certificates of attendance as proof of participation for 2 years.

The Board of Pharmacy, with the recommendations of an Advisory Council, will approve all continuing education programs for Maryland pharmacists which will be submitted to the Board on a designated sponsorship form. The Board has the ability to grant a "hardship" exemption to pharmacists unable to complete the C.E. requirements due to circumstances beyond reasonable control.

An individual pharmacist may sponsor a C.E. program for himself for credit, in the event it has not already been sponsored by the presentor, either before or after the program takes place.

All of these various features of the bill are designed to make it flexible and yet responsible to the educational needs of Maryland pharmacists

Mandatory Continuing Education will be another tool that is available to pharmacists in their quest for self-improvement. Ultimately, it is up to each pharmacist to determine his or her own educational needs and choose from the variety of subjects, methods of presentation, and intensity of study provided by mandatory continuing education.



Forward
your comments
to MPhA
Legislative
Committee

DRAFT

Continuing Education Bill

SECTION 1 Be it enacted by the General Assembly of Maryland that new section \_\_\_\_\_\_ be and it is hereby added to Article 43 — Health, of the annotated Code of Maryland to read as follows:

Article 43 — Health

SECTION

a) In order to advance a state of current professional and scientific knowledge and the continuing competency of pharmacists licensed in this state, the requirement for continuing pharmacy education is established.

Continuing professional pharmacy education shall consist of post graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, cassette programs, programmed learning courses, journal readings, audio-visual programs or such other form of continuing professional education as may be approved as herein provided.

The broad scope of professional pharmacy education includes subject matter pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms, and the etiology and characteristics and therapeutics of the disease state. It may include, but shall not be limited to the following: Pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmaceutics, professional practice management, anatomy, toxiology, histology, and other subject matter as may be approved as herein provided.

b) Requirements for continuing education. No license renewal shall be issued by the Maryland Board of Pharmacy to a pharmacist pursuant to until such pharmacist shall have submitted to the Board satisfactory evidence that he has acquired 30 hours of approved continuing education credit hours, (3.0 Continuing Education Units, C.E.U.), during the biennium immediately proceeding the date of such license renewal.

A continuing education unit (C.E.U.) is defined as ten contact hours of participation in an organized continuing education experience under responsible sponsorship, capable direction, and qualified instruction and which is approved by the Board. The continuing education biennium shall be that time period consisting of two years ending 90 days before the deadline for license renewal.

All continuing education program hours must be evaluated and accepted by the Maryland Board of Pharmacy. Application for approval of a continuing education program may be made by an association, corporation, education institution, organization or person to have such program designated as an accredited program and shall be made on a form designated by the Board.

The provider of sponsor seeking approval shall be required to meet the following criteria:

- Plan the activity or program after an assessment of the needs of the target audience has been made.
- 2. State the objectives and rationale of the program.
- The program must be of an instructional nature, pertinent to the practice of pharmacy and contribute to the knowledge or ability of the participants.
- The program content must be presented in an organized and sequential manner by a qualified instructor or resource.

- The provider will provide a means for registration by the participants and a record of participation will be maintained for a period of 3 years.
- There will be a method of program evaluation established that is suitable to the type of program being presented.
- 7. The fee to the participant and what is provided for that fee will be stated in advance of presentation of the program.
- The provider will furnish to each participant adequate documentation of his/her satisfactory completion of the program to include the following information.
  - a. Name of participant
  - b. Name of provider
  - Type of course of program (Seminar, correspondence course, workshop, etc.)
  - The number of continuing education units completed
  - e. The date of completion

All program changes must be made to and accepted by the Maryland Board of Pharmacy or the evaluation and acceptance of the program becomes null and void.

Programs may be submitted for evaluation by the Board from a participant after presentation or participation upon written request. Members of the Board shall have the authority to attend and participate in any continuing education program approved by the Board for continuing education credit.

c) Advisory council. An advisory council on continuing education shall be appointed by the Maryland Board of Pharmacy from lists of pharmacists submitted by individual pharmacists and/or pharmacy organizations. The number of members shall be selected by the Board and shall serve for a period of two years. (Recommend 8 to 10).

d) Pharmacist requirements. Pharmacists licensed by the Maryland Board of Pharmacy shall have the responsibility to obtain 30 hours of continuing education credit hours from programs accredited by the Board per biennium and to report such participation or attendance to the Maryland Board of Pharmacy during the next license renewal period.

A Pharmacist shall retain a file of certificates and records of attendance or participation in accredited continuing education programs for a period of two years after the submission of the application for relicensure in the biennium in which the program occurred.

Continuing education credit hours awarded to the pharmacist by a pharmacy regulatory body of a state requiring continuing education other than Maryland in which he or she is registered to practice, will be accepted by the Board at the stated value.

Hardship exemptions from the requirements of this section may be granted by the Board of Pharmacy upon receipt of evidence that the individual was unable to complete the requirements due to circumstances beyond his control.

Pharmacists who are newly licensed to practice pharmacy in Maryland pursuant to section \_\_\_\_\_\_ of this act shall have their continuing education credit hour requirements pro rated per month from the date of licensure until the end of the biennium in which registration originates.

Continuing education credit will be given only once for each program per participant.

SECTION 2 And be it further enacted that this act shall take effect January 1, 1979.

JANUARY, 1978

## **COLBY PROCLAIMS** WOMAN SUFFRAGE

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MILITANTS VEXED AT PRIVACY.

Wanted Movies of Ceremony, **But Both Factions Are** 

WASHINGTON, Aug. 24 1920-



## Social Security Bill Is Signed Gives Pensions to Aged, Jo

Roosevelt Approves Message Intended to Benefit 30, Persons When States Adopt Cooperating Laws-He the Measure 'Cornerstone' of His Economic Progr

## SENATE APPROVES 18-YEAR OLD VOTE IN ALL ELECTIONS

Amendment to Constitution is Sent to House. Where Passage is Expected

WASHINGTON, March 10, 1971-The Senate approved

WASHINGTON, Aug. The Social Security Bill, a broad program of unen insurance and old age and counted upon to be 20,000,000 persons, becan day when it was signed dent Roosevelt in the p those chiefly responsible ting it through Congress

Mr. Roosevelt cal "the cornerstone



## the Dra Ends No

WASHINGTON, Jan. 27, 1973-"With the signing of the peace agreement in Paris today, and after re-ceiving a report from the Secretary of the Army that

## TRUMAN CLOSES VITED NATIONS CONFEREN WITH PLEA TO TRANSLATE CHARTER INTO DEEDS

## NEW WORLD HOPE

President Hails 'Great Instrument of Peace,' Insists It Be Used

HISTORIC LANDMARK

Meeting Gives Standing Ovation as Executive **Pictures** Peace Gain

"If we fail to use it," he declared to the solemn final meeting of the delegates, 'we shall betray all of those who have died in order that we might meet here in freedom and safety to create it.'
."If we seek to use it selfishly—for

the advantage of any one nation or any small group of nations—we shall be equally guilty of that be-trayal."

Pervent Interpolation
The President, speaking in the auditorium of the War Memorial Opera House, built in memory of sons of the Golden Gate city who gave their lives in the first World. War, in which he himself served, seemed to give unconscious expression to the solemn feeling of the occasion when, at the outset of his speech, he interpolated the words.

Just before the plenary session President accompanied the

## PATIENT PACKAGE INSERTS: A CONCEPT WHOSE TIME HAS COME?

The consumer's right to know is an ir reversible and desirable trend of the Seventies. It extends, and properly, to a patient's right to know more about his or her prescription medications. One way, gaining favor, is through patient package inserts. Wisely-prepared and properly distributed when medically indicated, they could markedly improve patient knowledge and drug therapy—laudable goals by anyone's standards.

The PMA endorses these goals and will work with government, the health professions and consumers to achieve them.

#### The Advantages

The concept holds promise of benefits: better patient understanding of the product prescribed, better adherence to the treatment plan, and more awareness of possible side reactions.

Every doctor has had patients who fail to finish antibiotic regimens because they feel better. Some patients assume that if one tranquilizer or analgesic is good, two may be twice as good. Still others fail to report dizziness while on antihypertensive therapy—and so on.

Problems like these might arise less often if the patient received written information in addition to verbal instructions. Some studies suggest that patients are more receptive to such materials, and they more often understand the verbal instructions and follow them, when inserts are used.

#### The Disadvantages

There are also some potential problems. Obviously, the inserts must be clearly phrased, without extraneous or complex detail. How much information is enough? How can it be kept current? Should all patients receive the same information? Should inserts be included with all drugs? Should only potential problems be listed or are patients better off with a "fair balance" presentation that describes usefulness as well as drawbacks?

These and similar questions require answers, since model inserts have yet to be properly developed and tested. Despite the need for these studies, the FDA is proceeding prematurely with inserts on selected products. We think the Congress is the only place where the matter can be given the proper legal status and direction, particularly since it represents a conceptual change in the legal, medical and social framework of the nation's prescription drug information system.

#### The Solution

The PMA believes that carefully-devised pilot studies of various kinds of inserts are needed. They should be developed and implemented with full participation by doctors, pharmacists, consumers, communications experts and the drug industry. Such studies will provide reliable pathways to follow, so that inserts will be useful aids to medical practice.

And particularly we think that you should be closely involved in this debate and in these studies and decisions. Otherwise, people with less experience and qualifications may control the purposes, content and use of a tool with considerable promise for improved patient care. It could make a difference in your practice tomorrow, and more importantly, in the health of your patients.

#### AING

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## "My people are honest!"

by Thad L. Weber, Security Consultant, SK&F Laboratories

It's only natural for the small-businessman to reach the conclusion that his employees are honest since, in fact, 95% of the people he knows—his family, friends and customers—are honest.

But crime statistics support a lower employee integrity quotient, and examiners experienced in the use of polygraph and written integrity testing can substantiate the warning that as many as three to five out of every 10 employees require supervision to eliminate temptation.

There's no room for "instinct" in a high-risk situation. The pharmacy, no matter what its size, is a high-risk location. There are cash receipts, high value items such as watches, cameras, perfume, cosmetics, jewelry and appliances, and controlled substances. The theft of the latter may jeopardize the pharmacist's license to dispense drugs—the jugular vein of his business.

The pharmacist must deter internal theft. This problem should be approached from two directions:

- 1. procedures designed to select only applicants with a high integrity quotient
- controls which will deter most thefts and detect promptly those that might occur

Employee Selection. In 75% of the States, a pre-employment polygraph examination may be used to confirm an applicant's skills, health, work habits and job interests, as well as the applicant's integrity.

In any area, special written tests may be administered to applicants to measure honesty and attitude toward crime.

In some cases personal interviews

with a previous employer and the applicant's neighbors may be effective. However, few written form-type replies to reference requests provide complete information concerning an applicant. You should assume that the persons listed by an applicant as personal references are certain to make favorable statements.

Bonding applications required by some insurers and selective procedures used by pharmacy boards are not adequate integrity verification techniques either. Since these are not performed by the pharmacist, they may not be complete or current!

Controls to deter or detect theft are equally important. While specific details will vary by pharmacy, the following suggestions will generally apply to all locations.

- A company policy clearly presented to all employees dealing with:
  - a. prosecution of criminals
  - b. unauthorized use of company funds, e.g., cash register i.o.u.'s
  - c. the taking of, or use of company property
- 2. Effective record keeping, including:
  - a. prompt checking of incoming merchandise and movement to storage; discrepancies reported and investigated immediately
  - b. planned physical inventories, at least twice a year
  - c. random on-the-spot physical inventories of critical items
  - d. employment of an "outside bookkeeper or audits by certified accountants

- 3. Cash register controls including:
  - a. sealed tapes with key restricted to proprietor
  - b. signs requesting that customers verify all receipts
  - c. formal procedures for balancing the register any time another employee assumes the "check out" role
  - d. frequent reconciliation of register receipts and deposit of accumulated cash surplus
  - e. use of two employees at the check-out counter
  - f. installation of mirrors, cameras, closed circuit TV in check-out area
  - g. procedures requiring supervisors' approval of all credits and refunds
- 4. Prescription department controls would specifically include:
  - a. procedures restricting access to licensed pharmacists only
  - b. maintenance of controlled substance reserves under key lock control
  - c. strict narcotics safe key or combination control
  - d. special seals on controlled substance containers scheduled for delivery to customers
  - e. logs recording all courtesy transfers between pharmacists

Internal security is never a pleasant task to plan, but it is one which must be handled effectively. Don't put yourself in the position of one retailer whose employee, convicted of one of many thefts accomplished over years of service, accused the proprietor of contributing to the crime by failing to curb the temptation to steal!

JANUARY, 1978

Paramount Photo Service

THE MARYLAND PHARMACIST



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employer, in connection with said law suit, and the assumption by **Geigy** Pharmaceuticals, where appropriate, of the defense of the action through its own attorneys.

This agreement by **Geigy** Pharmaceuticals to indemnify and hold harmless, as set forth above, is expressly conditioned upon the pharmacist, or his employer, immediately notifying the Company of any claim, demand, or the service of any complaint. This



## and every pharmacist who dispenses it.

preement is further expressly conditioned on the pharmacist, his employer, providing full poperation to the Company, inuding complete access to all elevant records, and on Geigy narmaceuticals having complete control over the conduct and disposition of any claim, demand, law suit.

This agreement is not applicable if Geigy Pharmaceuticals determines that there is evidence of any improper or negligent statement or act, or omission to act, by the pharmacist, or his employer, or if Geigy Pharmaceuticals determines that there is evidence that the product has not been properly stored or properly dispensed.

**Geigy** Pharmaceuticals Division of CIBA-GEIGY Corporation Ardsley, New York 10502

# Dependability

The "McNeil" signature on every TYLENOL with Codeine tablet that you dispense is your guarantee that we stand behind you with our assurance of quality, purity, and accurate formulation.

For a full statement of our Pharmacist's Protection Policy, please write to: Director, Trade Relations, McNeil Laboratories, Inc., Fort Washington, PA 19034.

## Dispense the leader... TYLENOL ( tablets

Tablets: contain codeine phosphate\*: No. 1-7.5 mg ( $\frac{1}{6}$  gr); No. 2-15 mg ( $\frac{1}{6}$  gr); No. 3-30 mg ( $\frac{1}{2}$  gr); No. 4-60 mg (1 gr)—plus acetaminophen 300 mg.  $\frac{1}{6}$  Warning: May be habit forming.

†Data available from an independent research service show TYLENOL with Codeine tablets to be the most frequently prescribed narcotic-containing analgesic combination.

Contraindications: Hypersensitivity to acetaminophen or codeine

Contraindications: Hypersenstivity to acetaminophen or codeine. 
Warnings: Drug dependence: Codeine can produce drug dependence of the morphine 
fire and may be abused. Dependence and tolerance may develop upon repeated 
all tration; prescribe and administer with same caution appropriate to other oral 
Subject to the Federal Controlled Substances Act. 
If an an in atory patients: Caution patients that codeine may impair mental and/or 
all abilities required for performance of potentially hazardous tasks such as 
all act or operating machinery. 
The subject is a constant of the subject I ree in premain y. Safe use not established. Should not be used in pregnant women

Precautions: Head injury and increased infracranial pressure: Respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exagger ited in the presence of head injury, other intracranial lesions or a

pre-existing increase in intracranial pressure. Narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute abdominal conditions: Codeine or other narcotics may obscure the diagnosis or

clinical course of acute abdominal conditions

Special risk patients: Administer with caution to certain patients such as the elderly or debilitated and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

Adverse Reactions: Most frequent: lightheadedness, dizziness, sedation, nausea and

vomiting; more prominent in ambulatory than nonambulatory patients; some of these reactions may be alleviated if the patient lies down. Others: euphoria, dysphoria,

Drug Interactions: CNS depressant effect may be additive with that of other CNS

depressants. See Warnings.
For information on symptoms and treatment of overdosage, see full prescribing infor-

McNEIL McNeil Laboratories, Inc. Fort Washington, Pa. 19034

## **Drug Product Problem Report**

The case studies presented below are intended to serve as examples of the kinds of action that may be taken through the Drug Product Problem Reporting Program. While these results are from actual reports received, they are included for general illustrative purposes only. It is hoped that these examples will indicate to the pharmacist reader some of the areas where he or she may want to be alert. No reflection on any specific manufacturer, distributor, pharmacist, or product is intended or should be inferred from the case studies.

#### Sulfur-Alum Mixup

An Alabama community pharmacist was alerted by a customer that a package purchased at a grocery store labeled as powdered ammonium alum did not contain alum. The pharmacist suspected the contents to be sulfur, which as he indicated "could pose a potential problem since alum is used this time of year for pickling and sulfur could even be fatal to a person who is highly allergic to it." An inspection of the repacker's facilities disclosed poor label controls that were probably responsible for the error. Wholesalers were directed to recall to the retail level.

#### Product Mixup

The manufacturer of an OTC antihistamine-decongestant recalled the product after a California community pharmacist reported finding a sealed bottle containing tablets that appeared to be the same as those in a bottle of an OTC analgesic made by the same company. The pharmacist received both bottles at the same time and noted that they even had the same lot number. Laboratory analysis confirmed his observation that the drugs were the same. This recall was classified as a significant health hazard and extended to the physician/retail level.

#### FDA Unaware

Conflicting expiration dates were noticed on the carton and unit doses for tetracycline capsules by an Ohio pharmacist. The exterior label listed January 1978 as the expiration date while the unit dose was marked January 1975. Replacement of the cartons with the correct label was made by the firm's sales force. Although the firm had discovered the discrepancy in April 1974, FDA was not notified by the firm until after the receipt of the drug defect report in June 1975.

#### **Proprietary Name Changed**

Often it is difficult to correlate whether or not the reports we received had an impact on a manufacturer's decision to modify his product. In a recent instance, we received several reports from pharmacists informing us that the proprietary name for an antibiotic preparation might be confused with the proprietary name for a cardiac preparation. The manufacturer of the antibiotic preparation has since changed the proprietary name.

#### Possible Oxidation During Operation Procedure?

A hospital pharmacist reported problems in obtaining satisfactory anesthetic levels during various surgical procedures utilizing a diluted lidocaine solution.

The firm re-analyzed the lot, and the results were all well within specifications. The firm in its letter commenting upon the dilution procedures utilized during surgery brought up a point that we believe may be interesting:

"We flush each vial with nitrogen prior to sealing to displace the air and provide for a more inert atmosphere, yet, it seems that using the diluted injection from an open stainless steel bowl allows for metallic as well as oxidative processes to have an unknown effect on the product."

#### **Expiration Dating Added to Carton**

A California pharmacist wrote to recommend that the expiration date be placed on the outside of the container as well as on the crimp of an ointment tube because (1) when the patient rolls up the tube the expiration date is no longer visible and (2) pharmacists will thereby be less likely to dispense outdated merchandise. The manufacturer agreed, and altered its packaging directives; and the expiration date will appear in both places.

#### **Bottle Cleansing Procedure Improved**

An Illinois community pharmacist reported receiving a "dime"-sized piece of glass in a bottle of 100 tablets. Upon receipt of the report, the firm investigated the equipment used to "blow out" all bottles immediately prior to filling. It seemed that an air tube on the machine partially blocked the mouth of the bottle. Thus, large objects could remain in the bottle, while smaller ones would be removed. The firm revised its procedures accordingly.

JANUARY, 1978

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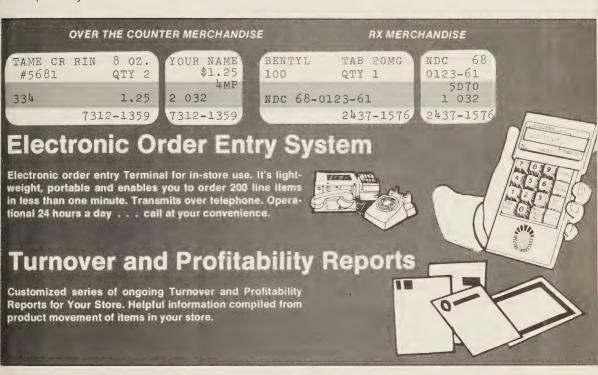
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JANUARY, 1978

21

## A Survey of Pharmacy Cost Data in Maryland

Bruce L. Myers, L. Darrell Stauffer, and Jacob W. Miller\*

#### Introduction

We are pleased that our firm has been awarded the contract to perform a survey of pharmacy operational data in the State of Maryland. This article contains a summary of (1) the objectives of the survey, (2) the methodologies of cost finding to be employed, (3) office and administrative procedures that we have initiated to encourage quality control and safeguard confidentiality of survey data and (4) drafts of cost survey forms and instructions. Under the terms of the contract with the Maryland Department of Budget and Fiscal Planning our responsibilities are to survey and verify individual pharmacies' cost and other related data and from this analysis determine the costs incurred in filling a prescription. We have done similar work in Kansas during the past several years and in addition, we have performed the initial pharmacy cost survey in the State of Georgia. Our basic goal in the successful completion of this project is to remain fair and objective and to perform quality work that will withstand the scrutiny of critics.

This article was prepared for THE MARY-LAND PHARMACIST by the staff of Myers and Stauffer, Certified Public Accountants, 909 Topeka Avenue, Topeka, Kansas 66612. Their firm will be conducting a pharmacy cost survey in the next few months in Maryland. Mr. Myers and Mr. Stauffer are certified public accountants and have taught accounting at the university level for a number of years before going into public practice. Mr. Miller is a pharmacist and an attorney with many years of experience in community pharmacy. He is the President-elect of the American Pharmaceutical Association and is recognized as an authority on variable fee systems. All three authors have several years of experience with cost related pharmacy fee systems.

#### Objectives of the Survey

The purpose of the survey of pharmacy operational data is to determine actual costs incurred in the dispensing of pharmaceutical prescriptions (other than ingredient costs) in the State of Maryland. One of the motivating factors for the study is the recent federal legislation [45] CFR 250.30(b)(2)] which requires that states consider results of surveys of cost data in determining reimbursement systems and rates to be adopted for providers of pharmaceutical products under the Title XIX (Medicaid) program. We believe that the intent of this legislation is for reimbursement rates, in this case, professional fees for pharmacies, to be responsive to the costs of providing pharmaceutical services.

The Maryland Department of Budget and Fiscal Planning has charged us with the responsibility of gathering and analyzing cost and other related data. The success of the entire project will depend to a large degree on the cooperation of each pharmacy chosen to participate in the survey. This cooperation will benefit all Maryland pharmacists in as much as the finished report is expected to be used as a basis for future dispensing fee determinations in the Medicaid program. It is the sentiment of some pharmacists in Maryland that in many cases the costs incurred in filling a prescription are greater than the current \$2.25 fee allowed. If this hypotheses is borne out by survey results, the data generated should provide relevant support for an increase in the professional fees paid for Title XIX prescriptions in the future.

We are quite concerned about the ease with which survey forms can be completed by the pharmacy provider realizing that one must always balance the additional information obtained from a more complicated form with the inconvenience, cost and frustration to the pharmacist who must fill it out. We believe that the survey forms which will be used achieve this balance. Only information which is essential to successful completion of our task has been requested. A two page form has been tested in other states and found to be an acceptable length. Survey forms and instructions to be used were developed after meetings with State and Maryland Pharmaceutical Association officials. In an effort to obtain accurate information and to make the forms more convenient to complete. all expense line items have been referenced to line numbers of appropriate federal income tax forms. Our experience indicates that the federal tax reference line number is a great aid in completing the survey form.

#### Methodologies of Cost Finding

The basic analytical rationale that will be utilized is full costing. Under full costing, all costs associated with a particular operation are added together to find total cost. If unit cost is desired, total cost is divided by the total number of units produced or serviced during the same time period. In general, this is the same rationale used in generally accepted accounting principles and for income tax purposes. Cost finding is the recasting of cost data through the use of rules or formulas in order to accomplish an objective. Prescription costs are

<sup>\*</sup>Editor's Note:

composed of ingredient costs, labor costs and overhead costs. In the case of the instant project, the object is to estimate the average cost of dispensing prescriptions, not including ingredient cost, on a unit basis. Therefore, all costs associated with filling prescriptions in a particular pharmacy will be summed so as to determine total cost. The total number of prescriptions dispensed during the reporting period will then be divided into the total cost so as to arrive at the cost per prescription during the reporting period.

Overhead cost per prescription is calculated by adding together the allocated overhead cost items and dividing this sum by the total number of prescriptions dispensed. Labor cost per prescription can be calculated by allocating the total salaries, payroll taxes, and benefits on the basis of percent of time spent in the prescription department and dividing this sum by the number of prescriptions dispensed. If such time allocation information is not available or is unreliable, revenue allocation methods will be substituted. Various classifications fo salaries and wages are on the cost report form in order that appropriate cost treatment can be given to different types of employees or owners.

#### **Administrative Procedures**

Pharmacies to be surveyed will be selected at random and will be mailed instructions and cost survey forms from our Topeka office. It is imperative that each surveyed pharmacy be as accurate as possible in providing cost information. We think that all parties concerned will be influenced more by an accurate report reflecting objective costs than a report containing inaccurate or subjective data.

The confidentiality of all cost report information is of great importance. The completed survey forms will be assigned random identification numbers when they are received in our office. Name, medicaid provider number, and other ownership information will be separated from the remainder of the data provided by each responding pharmacy as an added precaution in preserving the confidential nature of the survey information. Access to the matching

of ownership information to cost report data will be under the personal control of the partners and will not be revealed in the finished report.

After the initial processing of the

cost reports in our office, the accounting staff will analyze cost and other data for reasonableness. Guidelines utilized for this review will include generally accepted accounting

Mye Certified 909 Topek	or ending on or before December I systems Designed E rs and Stauffer Public Accountants Topeka Avenue (a, Kansas 66612 (13) 233-3637		rovider Number
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principles and normal business practices for the profession. Additional information will be requested from the pharmacy if data submitted appears to be inaccurate or incomplete. It is our experience that some of the cost reports will require either a telephone contact or written communication to the pharmacist or his accountant for clarification. Certain data from the completed survey forms will be keypunched so that the speed and accuracy of electronic data processing can be utilized. Relevant statistics and arrays of data will be generated for our analysis.

Pharmacies participating in the survey will later receive an individual computerized report showing how costs were allocated and how their cost per prescription was calculated. This report will reflect our analysis of the costs incurred by that individual pharmacy in filling a prescription. It is also a check on the accuracy of our work. If you detect errors on the printout you should call it to our attention. The computer analysis could be used by a pharmacist to determine his operational success or inefficiencies by comparison to other relevant data concerning all pharmacies surveyed. We hope to make this summary information available to you through a subsequent article in THE MARYLAND PHARMACIST.

A useful exercise for a pharmacist to perform when he receives the computer analysis is to compare his particular prescription data with the average and percentile information for all pharmacies surveyed. This may give some indication of problem areas in which it may be profitable to concentrate some additional professional and managerial effort. For example, if total cost per prescription is about average but labor cost per prescription is high, it might be a good idea to consider ways of reducing labor cost per prescription. Alternatively, one may find that labor and overhead cost per prescription are well within acceptable limits but that gross margin is low. A low margin implies that one should direct some attention toward pricing policy (and to a lesser extent purchasing policy) in order to improve gross margin. As a management tool, this procedure is

extremely crude and it does not indicate specifically what should be done. At best, these comparisons may only indicate problem areas for further attention and analysis.

In conclusion, after participating in meetings with representatives of the Maryland Pharmaceutical Association, the Maryland Department of Budget and Fiscal Planning, and the Maryland Department of Health and Mental Hygiene, we find that all groups involved are enthusiastic in their support of this program. We in turn look forward to working with the individual pharmacists in Maryland and producing a report which will be of benefit to the State of Maryland and to its providers of pharmaceutical services.

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20	21	Depreciation				29		
17	17	Taxes (see instructions)						
		Real Estate		X		30		
		Personal Property State Income (Corporate		* * * * * *		31		
		Other (Not Payroll or Sa			.^_^_^	33		
15	16	Rent .				34		
19	14	Repairs				35		
24	26	Insurance				36		
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23	25		(1) (2)	& WAGES (3)	(4)			
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		Owner Pharmacists				38		
		Owner Not Pharmacists				39		
		Other Rx Employees				40		
		All Other Employees	XXXXX XXXXX			41		
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18	15	Bad Debts				46		
	19	Contributions (Corporations	only-see instruction	ons) .		47		
24	26	Other Business Expenses n		e:				
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		Specify						
25	27		, line B, column 2			56		



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#### In Memoriam

#### Dean Noel E. Foss

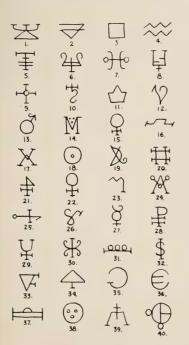
Noel E. Foss, who was Dean of the University of Maryland School of Pharmacy for 19 years until his retirement in 1968, died Tuesday, December 13, 1977 in Mesa, Arizona after a lengthy illness. Dr. Foss was 72 years old and is survived by his wife, the former Mildred Elsberry.

Dr. Foss, a native of Henry, South Dakota, graduated from Henry High School in 1923. In 1929, he earned his undergraduate degree in pharmacy from South Dakota State University and in 1933 was one of the first persons to receive a Ph.D. in Pharmacy from the University of Maryland.

His career began in 1934 as a professor of pharmacy at Duquesne University. He was head of the chemical department at Burroughs-Wellcome Company from 1937-1942, when he entered the Army. In 1946, he left the service with the rank of major and joined the Calco Chemical Division of American Cyanamid Company. In 1947, he joined the University of Illinois pharmacy school as its Assistant Dean until returning to Maryland in 1949.

Dr. Foss made a tremendous impact on Maryland Pharmacy and will be missed by all who knew him.

#### **ALCHEMY SYMBOLS AND THEIR MEANINGS**



- 2 EARTH
- 3 FIRE
- 4 WATER 5 ANTIMONY
- 6 YELLOW SULPHURET OR ARSENIC 7 RED SULPHURET OR ARSENIC
- 8 POTASH
- 9 OIL
- 10 LEAD 11 BORAX
- 12 SPIRIT OR WINE
- 13 IRON
- 14 VINEGAR
- 15 CALAMINE
- 16 SPIRIT
- 17 GLASS
- 18 GOLD 19 VERDIGRIS
- 20 WINE
- 21 QUICKLIME
- 22 COPPER
- 23 COPPERAS
- 24 AQUA VITAE 25 MAGNESIA
- 26 MARCASITE
- 27 RED LEAD
- 28 POWDER
- 29 MERCURY
- 30 SAL AMMONIAC
- 31 SALTPETRE
- 32 COMMON SALT 33 AQUA FORTIS
- 34 SULPHUR
- 35 SILVER
- 36 STONES 37 TO SUBLIME
- 38 HUMAN SKULL
- **39 TUTTY**
- 40 OIL OF VITRIOL



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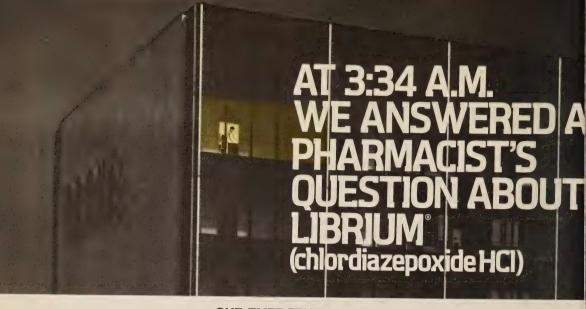
Last year, with help from our friends, we offered major aid at over 30,000 disastersfrom typhoons, to local (but just as devastating) house fires.

We were able to help the elderly with practical programs, we helped veterans by the hundreds of thousands, we taught people by the millions to swim or swim better. And that's just the tip of the icebera.

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And you'll know why we need your business as a Red Cross Volunteer. In your community. And all across America.Contact your local Red Cross Chapter to see how your company can become a volunteer.

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**Indications:** Relief of anxiety and tension occurring alone or accompanying various disease states.

**Contraindications:** Patients with known hypersensitivity to the drug.

Warnings: Warn patients that mental and/or physical abilities required for tasks such as

driving or operating machinery may be impaired, as may be mental alertness in children, and that concomitant use with alcohol or CNS depressants may have an additive effect. Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions), following discontinuation of the drug and similar to those seen with barbiturates, have been reported.

Usage in Pregnancy: Use of minor tranquilizers during first trimester

should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six. Though generally not recommended, if combination therapy with other psychotropics



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THE ANXIETY-SPECIFIC

seems indicated, carefully consider individual pharmacologic effects, particularly in use of potentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (e.g. excitement, stimulation and acute rage) have been reported in psychiatric patients and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depres sion; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship has not been established clinically.

Adverse Reactions: Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction; changes in EEG patterns (low-voltage fast activity) may appear during and after treatment, blood dyscrasias (includ-

ing agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making periodic blood counts and liver function tests advisable during protracted therapy **Supplied:** Librium® Capsules containing 5 mg, 10 mg or 25 mg chlordiazepoxide HCI. Libritabs® Tablets containing 5 mg, 10 mg or 25 mg chlordiazepoxide.



#### Lilly Digest Statistics for South Atlantic States

	1976 SOUTH ATLANTIC STATES	1975 SOUTH ATLANTIC STATES	1976 United States Average
Averages per Pharmacy	(216 Pharmacies)	(209 Pharmacies)	(1,705 Pharmacies)
Sales			
Prescription	\$ 177,210 54.0%	52.6%	49.6%
Other	150,842 46.0%	47.4%	50.4%
Tota1	\$ 328,052 100.0%	\$ 293,582 100.0%	\$309,725 100.0%
Cost of Goods Sold	210,782 64.3%	63,4%	64,9%
Gross Margin	\$ 117,270 35.7%	36.6%	35,1%
Expenses			
Proprietor's or Manager's Salary	\$ 24,097 7.3%	8.3%	7.3%
Employees' Wages Rent	41,014 12.5%	12.5%	11.8%
Miscellaneous Expenses	7,233 2.2% 33,134 10.1%	2.2%	2.5%
Total Expenses	\$ 105,478 32,1%	9.9%	31.5%
Net Profit (before taxes)	\$ 11,792 3.6%	3.7%	3.6%
Total Income of Self-employed Proprietor			
(before taxes on income and profits)	\$ 35,889 10.9%	12.0%	10.9%
Value of Inventory at Cost and			
as a Percent of Sales			
Prescription Other	\$ 21,421 12.1%	11.4%	12.1%
Total	31,199 20.7% \$ 52,620 16.0%	21.1%	20.8%
a or to or a	\$ 52,620 16.0%	16.0%	16.5%
Annual Rate of Turnover of Inventory	4.1 times	4.1 times	4.1 times
Number of Prescriptions Dispensed			
New	14,934 45.9%	46.1%	47.3%
Renewed Total	17,627 54.1% 32,561 100.0%	53.9%	52.7%
	32,361 100.0%	100.0%	100.0%
Prescription Charge	\$5.44	\$4.90	\$5.66
Number of Hours per Week			
Pharmacy was Open	67 hours	66 hours	65 hours
Worked by Proprietor Worked by Employed Pharmacist(s)	51 hours	51 hours	50 hours
worked by surproyed rharmacist(s)	42 hours	38 hours	37 hours



Single copies of the APhA poster together with additional material on National Poison Prevention Week 1978 are available free of charge from the Secretary, National Poison Prevention Week, P.O. Box 1543, Washington, D.C. 20013.

Quantities of the poster can be purchased from the Order Desk, American Pharmaceutical Association, 2215 Constitution Avenue, N.W., Washington, D.C. 20037. 25 for \$6; 50 for \$10; 100 for \$18; 500 for \$80; and 1,000 for \$140. Postpaid. Payment must accompany orders.

#### **NARD Consumer Brochure**

The National Association of Retail Druggists has a new brochure designed to let consumers know the considerations which go into the pricing of a prescription.

Also pointed out to consumers in the new brochure are the services available from independent pharmacies and the education and professional qualifications pharmacists must possess. The name of the new brochure is "Your Independent Retail Pharmacy: What we can do for you."

The brochure is being made available to members of NARD for distribution in their stores. Prices are 10 cents a single copy and \$4.50 for quantities of 50.

Consumers are told in the brochure:

"Your pharmacist is interested in and capable of helping you to use your medications properly and intelligently, so that you can benefit most from their use.

"Most importantly, this assistance is not limited to prescription medication. He or she can help you with the proper selection of non-prescription, or so-called over-the-counter, medicines to help you make sure that your non-prescription medication will not conflict with any prescription medication you may be taking.

#### A.C.A. Offers New Services

Do your 1977 financial statements show the profitability you desire? If not, perhaps the following services from the American College of Apothecaries can assist you:

Determining Average Expense to Dispense a Prescription:

The American College of Apothecaries can help pharmacy managers analyze their individual prescription pricing information and furnish them with their average expense to dispense a prescription. The financial information and data that can be obtained from this analysis will be of significant value as the pharmacy manager constantly reviews pricing policies in the currently competitive market and strives to justify an adequate fee in private and government third party programs.

Financial Analysis and Budget Preparation:

The American College of Apothecaries can analyze your financial statements and assist you in identifying potential problems in the operation of your pharmacies. This service is also a valuable tool in developing a budget for the next fiscal year. For further information contact the A.C.A. office, 874 Union Avenue, Memphis, TN 38163.

## MSHP Plans Annual Pharmacy Seminar

The Maryland Society of Hospital Pharmacists has announced plans for its Thirteenth Annual Hospital Pharmacy Seminar to be held June 16, 17 and 18, 1978 at the Cascades and Motor House in Williamsburg, Virginia.

For more information concerning the Seminar con-

tact:

Mr. Vincent DePaul Burkhart Seminar Chairman Department of Pharmacy Services University of Maryland Hospital 22 South Greene Street Baltimore, Maryland 21201

#### Nominations Sought For Honored Alumnus Award

The President of the Alumni Association of the University of Maryland School of Pharmacy, William Weiner, has invited all Alumni members to submit nominations to the Honored Alumnus Award Committee by March 1, 1978, Names, along with biographical sketches, qualifications, and accomplishments, should be submitted for this award.

The award will be presented at the Annual Graduation Banquet on June 1, 1978. The Honored Alumnus Award Committee consists of Leon Weiner, Chairman, Henry Seidman and Harry Bass. Nominations should be sent to: Leon Weiner, 2704 Maurleen Ct., Baltimore, Md. 21209.

## Classified Ads

Classified ads are a complimentary service for members.

(send replies addressed: ad no. \_\_\_\_\_, M.Ph.A., 650 West Lombard St., Baltimore, Md. 21201)

#### PHARMACIST WANTED

Permanent, part time, 30 to 40 hours a week, evenings and Saturdays. Contact Mr. Powell, Powell Pharmacy, Columbia, Maryland, 997-1600.

#### POSITION WANTED

Wanted, full time position preferably in Landover, Md. area. References available. Joseph F. Gindlesberger, 3122 75th Ave., Apt. #1, Landover, Md. 20785.

Classified Ad #23

Pharmacist with background in hospital and community pharmacy wants 15 to 20 hours per week. Prefer Tuesday and Thursday afternoon or evening. Must be flexible to fit in with other work.

#### FOR RENT

Store for Rent. Pikesville Plaza Bldg., 600 Reisterstown Rd., Baltimore. 1000 sq. ft. in a Medical office bldg. 486-3900.

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Jan. 7-15: M.Ph.A. Trip to Martinique

Jan. 22: Upper Bay Association Banquet

Jan. 22: Anne Arundel Association Banquet

Jan. 29: Eastern Shore Association Banquet

Jan. 31: Prince George/Montgomery Association
Meeting

Feb. 12: BMPA Dinner Dance, Bluecrest

Mar. 5: Swain Seminar "Geropharmacy and Geriatric Medicine"

May 13-18: A.Ph.A. Convention — Montreal, M.Ph.A. Trip

June 1: Alumni Association Graduation Banquet

June 16-18: MSHP Annual Pharmacy Seminar, Williamsburg, Virginia

June 18-22: M.Ph.A. Convention — Carousel Hotel, Ocean City

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JANUARY, 1978

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Contraindication: Previous hypersensitivity to penicillin.

Warnings: Serious, occasionally fatal, anaphylactoid reactions have been reported. Some patients with penicillin hypersensitivity have had severe reactions to a cephalosporin; inquire about penicillin,

cephalosporin, or other allergies before treatment. If an allergic reaction occurs, discontinue the drug and treat with the usual agents (e.g., epinephrine or other pressor amines, antihistamines, or corticosteroids).

Precautions: Use with caution in individuals with histories of significant allergies and/or asthma. Do not rely on oral administration in patients with severe illness, nausea, vomiting, gastric dilatation, cardiospasm, or intestinal hypermotility. Occasional patients will not absorb therapeutic amounts given orally. In streptococcal infections, treat until the organism is eliminated (minimum of ten days). With prolonged use, nonsusceptible organisms, including fungi, may overgrow; treat superinfection appropriately.

Adverse Reactions: Hypersensitivity, including fatal anaphylaxis. Nausea, vomiting, epigastric distress, diarrhea, and black, hairy tongue. Skin eruptions, urticarla, reactions resembling serum sickness (including chills, edema, arthralgia, prostration), laryngeal edema, fever, and eosinophilia. Infrequent hemolytic anemia, leukopenia, thrombocytopenia, neuropathy, and nephropathy, usually with high doses of parenteral penicillin. [102178]

Additional information available to the profession on request.



Eli Lilly and Company Indianapolis, Indiana 46206

70004

#### THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association

FEBRUARY, 1978 VOL. 54 NO. 2



## **Drug Evaluations** —

Thomas C. Majerus, Pharm.D.

## **Podiatry and Pharmacy**

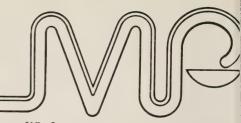
David Cohen, D.P.M.

## **Controlled Substance Thefts**

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FEBRUARY 1978

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NO.2

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Controlled Substance Thefts

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- Thad L. Weber

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## Discounts — A Different Viewpoint

At some time in the last decade, the plight of our nation's elderly became a focal point for concerned legislators and vocal citizen groups. A worthwhile solution to provide some supplemental assistance to "Senior Citizens" who were living on fixed incomes was the so-called "Senior Citizen Discount".

In general I am in complete sympathy with the idea of providing this additional benefit to those who are in need of such relief. There is, however, another side to this question of discount. First I believe, we must be concerned with other classes of our population in need of financial assistance. Without denying the need for help in the broad classification of those over 60 years of age, it must be recognized that many in that age group have accumulated a great deal of wealth.

In my practice, I see many patients who are between trips across the continent or across the ocean, who come in to refill prescriptions and obtain this discount. We must wonder how many of the young, married patients, struggling to make ends meet, are willing to subsidize this high standard of living for our affluent citizens.

Might not these young people, most of whom are lucky to find jobs, feel that they are a class of citizen entitled to a special "Junior Citizen Discount"? My own philosophy on the subject goes back to the traditional practice of the early community pharmacist. In the days before price posting and price advertising, etc., it was a general practice to give special prices to those least able to afford needed medications. Now that the price of "miracle or wonder drugs" is so astronomical, it is even more important that we be able to reduce our charges to the financially handicapped.

Can we do this by picking an age group or would it not be better to assist the needy? Helping the old at the expense of the poor makes me wonder if there is not a better way. Our energies should be spent in developing a "Special Citizen Discount". This would provide benefits to the lower income groups not entitled to public assistance and to any other hardship families to whom a discount would provide assurance of proper medical attention.

If you agree that the president of General Motors should not be given a discount just because he is 65 years of age, maybe you can help find a more equitable program.

How about a "Middle-age Citizen" discount?

Scharl Doar

### **Drug Evaluations**

# Racemic Epinephrine and Terbutaline Sulfate

by

Thomas C. Majerus, Pharm.D.

Clinical Pharmacology Maryland Institute for Emergency Medical Services Asst. Prof. Clinical Pharmacy

#### Racemic Epinephrine

- A. Generic name: racemic epinephrine
- B. Brand names and manufacturers:
  - 1) microNefrin Bird Corporation (Rx)
  - 2) Vaponefrin Fisons Corporation (OTC)
- C. Manufacturer's Recommended inidcations:
  Provides prompt bronchodilator effect for temporary
- relief from acute paroxysms of bronchial asthma.

  C. Pertinent Pharmacodynamics
  - 1) Administration and Dosage
    - a) Dosage: 0.2 to 0.4 ml (4 to 8 drops) diluted with distilled water 4.8 to 4.6 ml (100 to 80 drops) volume to a volume of 5.0 ml.
    - b) Administration
      - 1) IPPB
      - 2) Pocket Nebulizer: Hold nebulizer tip about 2 inches from mouth. Open mouth wide and inhale deeply, while squeezing the rubber bulb very hard. Unless a deep breath is taken at the same time that a very hard squeeze is given the bulb, the vapor will be wasted in clouds about the face. Take 2 or 3 inhalations, then rest 5 minutes to note effects.

#### E. Evaluation

By way of review remember that the adrenergic system has receptors that are different from each other depending on the organ system innervated. The bronchial tree is innervated by the beta-2 receptors and tremors are also caused by beta-2 stimulation. Beta-1 receptors are present in the heart. Stimulation of the alpha receptors results in blood pressure rises, pallor, urinary retention and perspiring.(13) Keeping these receptor locations and responses in mind is important when considering responses expected from epinephrine. Beta-1 stimulation results in increased heart rate, increase in cardiac force of contraction, increased conduction velocity, and decrease refractory period at the AV node. Beta-2 stimulation results in bronchial dilatation and dilatation of blood vessels.(15) Alpha adrenergic stimulation results in vasoconstriction. The beta-2 effects

are most desirable. This vasoconstriction could decongest a turgid bronchial mucosa and perhaps decrease blood supply to overactive mucosal glands but it also has accompanying systemic hypertensive effect.(4) It should be noted that the alpha adrenergic effect is exerted very readily when epinephrine is given parenterally. The beta-1 cardioaccelerating effect has no known redeeming feature.(4)

Epinephrine is the bronchodilator in nonprescription inhalers and exhibits only very transient effects in the dose used. (7) Beta-adrenergic stimulators have been the drugs most commonly used in controlling symptoms in the majority of asthmatics. Epinephrine has been one of the most useful of these drugs, and has been called the agent of choice for acute asthma. (1) However, epinephrine has shortcomings. It is not effective orally, has a short duration of action, and is not a pure beta-2 stimulator (therefore, has undesirable cardiovascular stimulation). (10)

All currently available preparations result in undesirable cardioactive and vasoactive effects in humans. (3) Promotion of a drug as a "selective beta-2 stimulator" may be misleading since it actually means relatively selective. There is no pure beta-2 stimulator in humans available. It can be very useful if used with caution in early acute asthma. It deserves mentioning that it is extremely dangerous to use epinephrine (inhalation or subcutaneously) after the patient has used a pocket sympathomimetic aerosol. (3) Patients generally do not report inhaler among their "medications taken". Therefore, before administering epinephrine ask specifically, "Have you used a spray inhaler?"

Epinephrine is sometimes ineffective in severe asthma, and to repeat the dose in the face of established refractoriness may induce restlessness and cardiac arrhythmias.(8) Hypoxemia may persist in asthmatic patients who are symptomatically improved with bronchodilator therapy. Epinephrine has been given to chronic wheezy asthmatic patients and it relieved airway obstruction but not hypoxemia.(17)

Voluntary hyperventilation in another group of asthmatics produced an increase in p02 whether or

not airway obstruction had been relieved.(17) The inefficacy of repeated doses of epinephrine by inhalation indicates that there is a local action on the airways that interferes with bronchodilatation.(2). The bronchotoxicity is mediated through the drug's effect on alpha adrenergic receptors.(15) It has been suggested that the broncho constrictor action resulting from alpha adrenergic stimulation by epinephrine could be relieved by administration of an alpha blocker such as phenoxybenzamine or tolazoline.(5) Inhalation of epinephrine is intended to reduce systemic reactions, but tachycardia can still occur as part of the sympathomimetic pattern of response. There is also a potential danger that cardiac arrhythmias resulting solely from absorption in the mucosal lining of sympathomimetic bronchodilator may de-

IPPB and racemic epinephrine therapy appears to be beneficial acutely for croup.(18) There is an immediate improvement in the signs and symptoms but then the patient's condition tends to relapse relatively rapidly (within two hours). If acute asthma bronchodilators are effective, they have been found equally effective in asthma whether administered with IPPB or a conventional nebulizer.(6) Furthermore, administering bronchodilators by IPPB is usually not as beneficial as one might hope. You are hoping for an increase in pO2 and a decrease in pCO2 and without oxygen therapy given concurrently, this end result might not be achieved.(14) To use IPPB without bronchodilators causes a decrease in ventilatory function marked by a fall in compliance and a rise in airway resistance possibly reflex in nature.(19,20) In comparing epinephrine subcutaneously, aminophylline IV, nebulized isoproterenol in IPPB with end inspiratory pressure of 15 cm water, physiologic saline in IPPB at 15cm pressure, isoproterenol in IPPB at 25 cm pressure, and physiologic saline at 25 cm pressure, there was statistically significant improvement with only subcutaneous epinephrine and IV aminophylline.(14)

Bronkosol is the product used at the University of Maryland for acute asthmatics for use in IPPB therapy. The ingredient with which epinephrine is compared and contrasted is isoetharine. Isoetharine has a high degree of beta-2 receptor selectivity. Because of this, it has much less liability toward cardiac side effects than has epinephrine, ephedrine, or isoproterenol.(11) Isoetharine can be given orally, however, this form is not available in the United States.

Bronkosol is combined with phenylephrine (a strict alpha adrenergic stimulant), in order to give it a longer duration of action, but, more importantly to obviate falls in arterial pO<sub>2</sub> due to ventilation/perfusion abnormalities, which would result from beta-2 stimulation alone.(16) (This results from pulmonary vasodilatation and will be explained subsequently.)

Relative to isoproterenol, epinephrine and isoetharine have the same bronchodilatory capacity, but epinephrine has three times the cardio accelerating potential as isoetharine. Isoetharine has no systemic vasopressor effect while epinephrine is the only agent available with systemic vasopressor effect. Due to its alpha adrenergic action epinephrine has the potential for minimal broncho-constrictor action, while isoetharine lacks this completely. (Remember that Bronkosol contains phenylephrine). Epinephrine contains roughly one-half the pulmonary vasodilation action of isoproterenol, but no information was found concerning pulmonary vasodilation with isoetharine.(4)

The pulmonary vasodilatation is important because it aggravates the ventilation/perfusion imbalance in the asthmatic lung producing more hypoxemia. Experimentally, epinephrine causes vasoconstriction on first infusion but vasodilatation follows after a few consecutive doses. Another problem with epinephrine and not with isoetharine is that of the laryngeal drying caused by epinephrine.(4) The manufacturer of racemic epinephrine indicates that rinsing the throat with water after inhalation helps prevent dryness.

Advantages of isoetharine are basically slightly fewer side effects than isoproterenol and epinephrine.(16) Isoetharine with phenylephrine has a duration of effect that is longer than isoproterenol(9,12). Also, the duration is longer than epinephrine. The duration of epinephrine is about one hour and that of isoetharine is one and one-half to two hours. Again the efficacy of isoetharine is just slightly better than that of isoproterenol and epinephrine mainly due to side effects.(16)

Because epinephrine self-treatment by asthmatics can put them in jeopardy if they over use the drug or if they fail to communicate that usage to the emergency room physician, epinephrine pocket aerosols should not be prescribed for asthmatics.(3) However, epinephrine aerosols, as well as epinephrine solutions and racemic epinephrine (Vaponefrin) for inhalation are OTC products. Once this fact is learned by the patient much of that patient's control has left the primary-care provider's hand

#### **Terbutaline Sulfate**

Terbutaline is being vigorously promoted as a beta-adrenergic receptor agonist that preferentially exerts its effect on the beta-2 receptors such as those which are located in the bronchial smooth muscle. By stimulating the beta-2 receptors sympathomimetic agents effect an increase in intercellular concentrations of c-AMP, which results in bronchodilatation. Aminophylline also produces an increase in c-AMP, resulting in bronchodilatation but its mechanism is different from that of the sympathomimetic amines. Aminophylline inhibits phosphodiesterase which degrades c-AMP; sympathomimetic amines result in an increase in intracellular adenyl cyclase which appears to act as a hormone-like stimulator of c-AMP synthesis.

The problem with terbutaline is that it is promoted as a beta-2 stimulator when it would be more correct to state

(Continued on page 8)

#### **Drug Evaluations**

(Continued from page 7)

that terbutaline is a *relatively* selective beta-2 adrenergic agonist. Promoters of terbutaline are correct when they indicate its preferential selectivity but the qualification in classifying terbutaline's activity is that its selectivity is not limited to beta-2 receptors and that concomitant beta-1 receptor stimulation results in the cardiac and vascular responses seen with terbutaline. The response of the heart to beta-adrenergic stimulation is increased heart rate, increased contractility, increased conduction velocity, and shorter refractory period at the A-V node. Beta stimulation in blood vessels results in dilation, which also results in reflex tachycardia.

Reliance on terbutaline for bronchodilatation in patients with congestive heart failure, coronary heart disease or hypertension may leave the physician (or the patient) with a false sense of security. *There is no pure beta-2 agonist available*. All sympathomimetic amines (including terbutaline) possess both beta-1 and beta-2 adrenergic receptor agonist activity.

The literature is replete with articles studying the effects of terbutaline. However, most of these studies compare 5.0mg dose of terbutaline with the 25mg dose of ephedrine. In a dose response study by Fagerberg and Tegner(3), a comparison was made with 2.5mg, 5mg, and 10mg oral doses of terbutaline and by misapplication of statistical analysis the authors concluded that 5.0mg dose was "apparently the appropriate single oral dose".

In a study by Dulfano and Glass(2), the authors state that terbutaline in 2.5mg doses resulted in significant improvement in pulmonary function parameters with no significant changes in heart rate or blood pressure. However, there was no difference between terbutaline 2.5mg and ephedrine 25mg. Therefore, ephedrine 25mg also resulted in significant improvement in pulmonary function parameters with no significant changes in heart rate or blood pressure. In addition, while the 5mg dose of terbutaline also produced improvement in pulmonary function parameters, this same dose produced a maximum increase of 10% in heart rate, more than the increase seen with ephedrine. The randomization of doses was adequate in this study and the levels of statistical significance are dependable.

In another study by Tashkin and associates(8), 5 mg terbutaline was compared with 25mg ephedrine. The mean increase in the FEV1 was not different between terbutaline and ephedrine and only ephedrine had a significant increase in FVC. The heart rate in the subjects was increased after both ephedrine and terbutaline. There was no statistically significant increase in heart rate between the two drugs except at one hour post dose when the heart rate increase seen with terbutaline was significantly greater than that seen with ephedrine. Ephedrine also produced no significant increases in systolic pressure while terbutaline did increase the systolic pressure by 4 to 9 mm Hg. Also a significant increase in pulse pressure was seen with terbutaline and not with ephedrine. The randomization appeared adequate and

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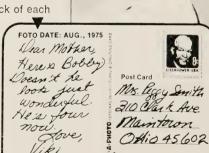
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the statistical analysis was sufficient for the comparisons that were made.

There are a few of the published studies, however, that state that terbutaline is "a most needed addition to our therapeutic armamentarium", (2)(4) but either use questionable statistics or fail altogether to outline the analysis by which the conclusion is reached.(5)(7)

There is a 1975 study (6), a copy of which hardly anyone with even a transient interest in terbutaline does not have, which shows terbutaline to be unbelievably superior to ephedrine. There are two reasons why this study does not deserve the widespread distribution it enjoys. First the study was supported by one of the manufacturers of the drug. In the interest of fairness and objectivity, it might be the better part of wisdom to have these studies conducted as independently as possible. Second, the students' t-test for paired values cannot be used to test for statistical significance when there are more than two variables. Here, there were six variables affecting the outcome of the study and it would be very difficult to achieve any results other than highly significant ones.

A subject which is addressed quite often is tachyphylaxis. Many note that tachyphylaxis has not been seen with terbutaline. There is no disagreement with that statement but it should also be made clear that no evidence has been shown that tachyphylaxis is a universal happenstance with ephedrine either. In a study (9) looking at the long-term (one year) effects of terbutaline and ephedrine, no tachyphylaxis was apparent with either drug.

In a paper by Dinda and associates, (1) the conclusion was that terbutaline was effective as a bronchodilator when given orally to patients with asthma. The conclusion is valid and similar conclusions have been reached elsewhere. The point to be made is not whether or not terbutaline is efficacious but whether or not terbutaline is to be preferred over ephedrine because of fewer incidental cardiovascular effects. Terbutaline has not been proved to be more effective than ephedrine as a bronchodilator.

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pregnancy has not been established. The use of the drug in pregnancy, lactation, or women of childbearing potential requires that the expected therapeutic benefit of the drug be weighed against its possible hazards to the mother or child.

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Adverse Reactions: Hypersensitivity, including fatal anaphylaxis. Nausea, vomiting, epigastric distress, diarrhea, and black, hairy tongue. Skin eruptions, urticaria, reactions resembling serum sickness (including chills, edema, arthralgia, prostration), laryngeal edema, fever, and eosinophilia. Infrequent hemolytic anemia, leukopenia, thrombocytopenia, neuropathy, and nephropathy, usually with high doses of parenteral penicillin. [102178] \*Equivalent to penicillin V.

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### **Podiatry and Pharmacy**

by

Dr. David Cohen Chairman, Podiatric Drug Committee Maryland Podiatry Association

In the ensuing article an attempt will be made to acquaint pharmacists with the practice of podiatry, medication often prescribed by podiatrists and how pharmacists might better serve their clientele in regards to foot health.

There are over 8,000 doctors of podiatric medicine in the United States. With his colleagues in medicine, osteopathic medicine and dentistry, the podiatrist is a member of one of the four professions permitted by law to prescribe and treat, medically and surgically, a part of the human anatomy. The podiatrist's scope of practice is defined in each state by law. He is licensed to diagnose and treat foot problems, to correct or revise deformities, to manage the pedal complications of chronic disease in cooperation with an attending physician, to treat injuries and deformities of the foot including the surgical correction of bones, muscles and tendons. But general podiatric care includes more. It includes the concept of prevention, the key to good pedal health.

The podiatrist is a graduate of an accredited college of podiatric medicine. He or she enters podiatry college with three to four years of undergraduate study and completes a four-academic year medical curriculum. During the last two years, much time is spent in clinical and hospital rotations. Upon completion of podiatry school, a graduate must pass either a national or state board of examination for license. Additionally, the podiatrist may complete a one, two, or three year hospital residency program.

The need for this branch of medicine is best explained by a simple fact: Foot disorders are among the most widespread and neglected problems affecting our society. They are a major cause of disability in 20 out of every 1,000 Americans, according to a survey by the Department of Health, Education and Welfare. The exact extent of less serious foot illness calling for professional care is not known, but it is estimated that for each person suffering actual disability there are at least 30 people with lesser forms of foot impairments.

The podiatrist is intimately involved with the health care of every family member. As specialists in the care of the foot, podiatrists are interested in the early detection and treatment of foot problems — the best way to prevent future disabilities, keeping people on their feet and walking without pain is vital to total health, both physically and emotionally.

Podiatry, to be sure, is linked with mental well-being, especially among the aged where the ability to walk is so essential to morale and personal independence. Among our elderly population, foot problems become more numerous and severe. So many of our elderly are home confined or disabled from easily treatable foot disorders.

Foot problems also plague the young. The maintenance of foot health among children is of extreme importance and can prevent many of the foot conditions seen later in life. Neglecting foot health in the early years invites problems not only in the feet, but also in the legs, lower back, and in other areas. The youngster with troublesome feet walks differently from his playmates, has poor general posture, and often avoids social and athletic functions as a result.

Podiatric services are not limited to any particular age group. Many community health programs are providing foot care services on a regular basis to a wide cross-section of Americans. The need for such care was summed up by Dr. Samuel L. Andleman, Commissioner of Chicago's Board of Health: "Podiatry is not just filling a gap," he said, "but actually a vacuum. In areas of general disease detection, here is an area where nothing, so to speak, is being done, and because of the importance of early detection, this is the profession that can help us the most."

It may be surprising to learn of the role the podiatrist plays in general disease detection, but the human foot often can reflect the body's general condition, and podiatrists are trained to be suspicious of many symptoms that routinely appear in the foot. These may mean trouble elsewhere in the body. As a result, podiatrists are often the first to detect diabetes, arthritis, heart disease, kidney ailments, and arteriosclerosis. Whenever the podiatrist discovers any of these symptoms, he consults with the patient's medical doctor concerning continuing treatment.

In general, the Maryland state law grants podiatrists the privilege to prescribe all classes of drugs. While the privilege is broad, most podiatrists as do other medical specialists limit their use of prescription drugs to those referrable to their specialty. Systemic conditions manifested in the foot are not uncommon. As an example, Rheumatoid arthritis or gout are often first detected by podiatrists during their examination of a patient's foot

(Continued on page 15)

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#### **Podiatry**

(Continued from page 13)

complaints and confirmed through appropriate laboratory studies. The role of the podiatrist rests in his treatment of the patient's acute symptoms rather than the total management of the disorder. The podiatrist may employ local steroid injections, short term courses of colchicine, Butazolidin or other anti-inflammatory drugs to relieve the patient's acute pain. The systemic nature of the problem relegates the total management of the patient to an internist and such a referral is then made. Similarly detected conditions such as hypertension, cardiovascular disease, hematologic disorders, G.I. disorders are best managed by a medical specialist rather than the podiatrist. Consequently, podiatrists, although familiar with all classes of drugs and licensed to prescribe them, rarely take on the responsibility of managing a patient's generalized medical health. Referral to the appropriate medical specialty is the rule rather than the exception.

At times, prescriptions are received by the pharmacist by podiatrists for drugs which have unusual uses. All drugs have specified indications and in general are used within the realm of their approved effectiveness. As with all medical specialties, certain drugs find special uses in the hands of the particular doctor and while known to the doctor become confusing to the pharmacist. It is my opinion that it is the obligation of the practitioner to inform his area pharmacists to be alert to those unusual prescriptions so that he can dispense the prescription with peace of mind. As an example, various anti-biotic/ anti-inflammatory eye/ear drugs are used by podiatrists for postoperative care of definitive nail procedures. A prescription written by a podiatrist with a signa of "as directed" might very easily be labeled by the pharmacist "To eyes/ears as directed." Needless to say, such labeled instructions to the patient will be confusing and upsetting, let alone of little value for his nail condition.

There are instances when podiatrists do indeed utilize those drugs most commonly prescribed by the internist. The post-operative patient with residual swelling might well be placed on oral diuretics and enzymes. The vaso-spastic patient or vaso-occlusive patient with a non-healing ulcer might be prescribed a vasodilator. The mildly improved patient with bursitis of the heel or fore-foot might be placed on a longer term of the non-steroid anti-inflammatory. It is therefore wise of the pharmacist to realize that the feet are indeed connected to the rest of the body and that prescribing by the podiatrist of all classes of drugs is sometimes necessary and appropriate.

The pharmacist quite frequently is the patient's initial and sometimes sole medical advisor. With the high cost of medical care, more and more people try to self-treat their maladies. While this often represents an economically feasible approach to rising costs of medical care, the patient is often being *penny wise* and *dollar foolish*.

While the advertising of over the counter products is for the most part substantive in its content, it is often misleading the public. While many of the foot remedies do indeed provide relief of symptoms, the relief is only temporary. The implication that various painful foot lesions and conditions are curable by certain plasters, creams, and drops often result in not only long term courses of therapy, but subsequent cost and possible exacerbation of the condition. While the majority of the population will have no adverse effect from the over the counter preparation, it is not the majority of the people that uses them. In most cases, the preparations are being used by elderly people and people with diabetes or circulatory disorders. In these people, where normal healing is already impaired, the inappropriate use of acids and blades could be hazardous. Not infrequently does the podiatrist or medical physician see a patient with a gross infection of the foot secondary to his self-treatment of an ingrown nail, corn or wart with one of the over the counter products.

The pharmacist can serve as a vital link between the podiatrist and the individual with a foot malady. When a pharmacy patron inquires of the pharmacist what is available to him to treat a specific foot problem, the indiscriminate dispensing of a proprietary product may not be in the best interest of the patient. It would be wise to dialogue with the patient over the nature of the problem and to advise him about seeking professional care should the over the counter remedy fail to provide relief within a few days. Rarely do over the counter products get to the cause of a problem, but rather they allow the patient to tolerate the condition. As an example, a product that implies that an ingrown toenail is treatable by its use topically is misleading. Quite possibly, a lot of the discomfort may be allayed, but the nail will remain ingrown and requires excision to provide any long term or permanent relief. Many other foot problems are afforded temporary relief with the proprietary products but require professional care if the patient desires the problem eradicated. Toothache drops relieve the pain, but the cavity in the tooth remains and requires professional care. The pharmacy patron would welcome your concern and advice.

In conclusion, an attempt has been made to acquaint the pharmacy profession with podiatry and the medications they most commonly employ. In so doing, it is hoped that the community can be better served by a closer understanding and rapport between the podiatrist and pharmacist.

DUES

FEBRUARY, 1978

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### Controlled substance thefts a matter of life and license

by Thad L. Weber, Security Consultant, SK&F Laboratories

Studies by federal and state drug law enforcement officers have revealed various abuses of the regulations at the pharmacy level ranging from theft for personal use to illegal distribution on the street.

Compliance audits at the pharmacy level have been limited by manpower availability and are likely to increase in scope and frequency as more state agencies are established.

Since failure to protect controlled substances from theft may result in the loss of your "license to dispense," you must take the initiative to prevent thefts and other abuses.

#### Theft by employees may be for:

- personal use
- a friend's personal use
- resale to other dispensers
- street sale profits

#### Other abuses include:

- dispensing without a prescription
- failure to confirm verbal prescriptions
- dispensing large quantities of controlled substances without investigation
- failure to safeguard prescription records

#### Analysis of pharmacy crimes reveals that the **theft of controlled substances may involve:**

- pharmacists
- other employees
- customers
- practitioners
- other visiting individuals, such as delivery truck drivers.

#### Drug thefts have been accomplished:

- from incoming orders along the delivery route between the supplier's stockroom and the pharmacy
- from open (or sealed) containers in the pharmacy storage cabinet or on the shelf
- by placing unauthorized orders to suppliers and then intercepting the delivery
- by altering, forging or counterfeiting prescription blanks or records
- by exceeding the quantity prescribed
- by unauthorized renewal of prescriptions in collusion with individuals supplying or prescribing controlled substances

### The pharmacy proprietor can prevent drug theft by:

- employing pharmacists of proven integrity
- requiring the same integrity tests for other employees who may have occasional access to controlled substances
- maintaining the prescription department restrictions detailed in last month's column (access, storage and key controls)
- instituting procedures for prompt reconciliation of incoming supplies by two assigned individuals
- running frequent physical inventories of critical items
- conducting random checks of factory seals on back-up stocks

- personally reviewing prescription logs for authenticity, quantity, frequency, user, etc.
- analyzing prescription department cash register sales

It's your business! That's sufficient reason for you to be personally involved in drug theft prevention. It's why most proprietors:

- handle a portion of the Rx department workload
- vary work schedules occasionally to prevent habitual and personal relationships from leading to drug abuse
- periodically measure the integrity of key personnel by further background investigation, polygraph examination, and the use of "shopping services"
- promptly investigate and resolve any shortages or irregularities and then immediately report losses of suspicious circumstances to law enforcement authorities
- MAKE VERY CLEAR THEIR INTENT TO PROSECUTE ANYONE INVOLVED IN THE THEFT OF CONTROLLED SUBSTANCES, SINCE THESE CRIMES MAY RESULT IN LOSS OF LIFE—THAT OF THE ILLICIT DRUG USER—AND YOUR BUSINESS!

17

# The straighter they talk, the better things get.



Fred M. Eckel, R.Ph., Assoc. Professor of Hospital Pharmacy Chapel Hill, N.C.



Sam McConnell, Jr., R.Ph. Community Pharmacist Scottsdale, Arizona



John Spicer, R.Ph. Community Pharmacist Fowler, Michigan



Benjamin F. Cooper, Ph.D., Dean, School of Pharmacy Auburn University, Auburn, Ala.



Don F. Gould, R.Ph., Chairman of the Board, Gould Drug Company Mt. Pleasant, Michigan



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Taylor H. Jobe, R.Ph Community Pharmacist Gladewater, Texas



Tom C. Sharp, Jr., R.Ph. Exec Sec., Tennessee Pharm, Assoc Nashville Tennessee



Don W. Arthur, R.Ph. Community Pharmacist Buffalo, New York

These days, any company that depends on "yes" men for advice is riding for a fall.

At Upjohn, the views of pharmacy are important to us.

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#### LETTERS



Dear Editor:

The State of Maryland has pre-filed amendments to the Pharmacy Practice Act which can only create more intimidations, harassments, and professional degradation by state officials who, in the past, have exercised their present police powers in arbitrary and even outrageous manners. The proposed amendments for license revocation institutes an administrative procedure that is legally informal, lacks subpoena powers, allows hearsay testimony, and otherwise does not demand the degree of proof provided by a court of law. Most importantly, the administrative judges are usually people who are politically allied with the State and thus may be easily controlled by the Attorney General's Office. The Court of Appeals has stated with few exceptions that no State court can substitute its judgment for the judgment of the Board. It is essential therefore that each proposed amendment be clearly justified as to need, and be viewed by all pharmacists in the light of the over zealous prosecutor and politicized board, rather than from the idealistic position of "they wouldn't do that to us."

The proposed action pursuant to amendments 7 and 8 describing the unauthorized dispensing and refilling of prescriptions should only be an issue before the Board upon the conviction of the pharmacist by a court of law. No quasi-judicial procedure should take the place of the Constitutional provisions of a jury trial. I submit that sections 7 & 8 would absolutely destroy professional judgments that a pharmacist might exercise in his practice. The need now and in the future for these sections is unfounded, unwarranted and unjustified. Section 14-15 describes report and records. Any report or record that is not correct is false. The question of whether or not it is a willful act becomes a question for the police powers of the Board. Any record or report that has not been made is an omission. The question of willfullness again becomes a question for the Board. This section could be the ultimate instrument for nit-picking and harassment by the state officials acting under the cover of this law.

Future Board demands, added to other State and Federal agency demands for records, reports and administrative procedures and/or actions related to the reports or records, could subject a pharmacist to constant Board disciplines. Looking at the State's past performance related to the enforcement of present record keeping requirements one can clearly see the future conflicts that would take place between the unreasonable and arbitrary demands of the State and the pharmacist's attempts to comply. Sections 16 describes professional, physical, and mental incompetence as a basis for licensure. There are extremes of mental and physical incompetence that no one would argue could endanger the public's health and welfare. However, the question of competence as a basis for one's right to earn a living strikes at the very soul of American freedoms. Will the State demand comprehensive retesting of all pharmacists each year? Will pharmacists be required to pass tests for physical agility or stamina? Will pharmacists be required to undergo mental testing designed to determine propensities toward drug use, emotional instability and possibly political extremism. Will the Board and all State officials be required to undergo the same tests for physical, professional and mental competence? If this were so I could almost agree with the legislation. I believe that the profession of pharmacy can and should regulate itself in this area until such time that the State can prove a clear danger exists to the health and welfare of its citizens in this matter. In the statement of need that proceeds the pharmacy practice amendments is the following: This bill will strengthen the procedures which are used by the Board of Pharmacy when taking disciplinary action against pharmacists. I find no procedures strengthened in the entire proposed legislation. We must critically ask those who proposed such changes: "How? and Why?"

M. Neal Jacobs, Pharmacist Laurel, Maryland

#### Editors Note

Mr. Jacobs is referring to the Department of Health and Mental Hygiene bill (H. B. 227) on the subject of Board of Pharmacy Discipline which appeared in the December, 1977 issue of the MARYLAND PHARMACIST on page 10.

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FEBRUARY, 1978

#### **Board Meets January 26th**



The M.Ph.A. Board of Trustees met January 26, 1978 for its first meeting of the new year. Members and guests who braved inclement weather and illness to attend were (left to right): Samuel Lichter, Frank Block, Philip H. Cogan, Leonard J. DeMino, Anthony G. Padussis, Ronald Lubman, (seated) David A. Banta, Richard D. Parker and Melvin N. Rubin.



S. Ben Friedman and Anthony G. Padussis await the start of the meeting.

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Your signature		

#### MedChi Committee Formed

The Medical and Chirurgical Faculty of the State of Maryland has formed a committee to develop methods for identification and rehabilitation of the impaired physician. A 24 hour a day Hotline has been established at:

Telephone: 467-4224

Pharmacists who, through their practice, become aware of physicians who are debilitated by chemical misuse or other problems, may contact the Committee on Physician Rehabilitation on the Hotline number. In situations where it would be beneficial to discuss the matter with a pharmacist familiar with the program, you may contact:

Mr. David Chason Telephone: (301) 727-5400, ext. 2413

All information and source of the information will be held in strict confidence. Speakers are available for meetings.

#### **Safety Closure Inspections**

The Department of Health and Mental Hygiene along with the Consumer Product Safety Council are now conducting inspections for compliance with the safety closure laws and at the same time soliciting pharmacists' comments about the law.

These inspections are not part of the routine drug control inspections and the Association recommends performing routine self-inspection for old packages which do not comply with the new standards.

Pharmacists are held liable under the Federal Poison Prevention Packaging Act of 1970 and the State of Maryland Act, Article 43, Sections 871, 872, 873 and 874, for the following:

Currently required to be in safety packaging are the following drugs:

- human prescription drugs in oral dosage forms with the exception of isosorbide dinitrale and nitroglycerine
- all controlled drugs in dosage forms intended for oral administration
- aspirin products, except for certain effervescent and powder forms
- 4. methyl salicylate (synthetic oil of wintergreen)

Other reluglated products which may be found in pharmacies:

- certain furniture polishes
- preparations containing potassium and/or sodium hydroxide (certain oven and drain cleaners)
- 3. turpentine
- 4. lighter fluid kindling and/or illuminating preparations
- 5. sulfuric acid
- 6. ethylene glycol (anti-freeze)
- 7. methyl alcohol (windshield washer solution)
- iron containing drugs or dietary supplements containing iron when the total amount of iron within the package exceeds 500 mg. (becomes effective June 1977)
- solvents for paint or other similar surface-coating material (removers, thinners, brush cleaners, etc.)

The law permits two ways to provide traditional conventional packaging:

 A manufacturer can market one size of the product in a conventional packaging if other packages of the same product are on the market in safety packaging. However, in these exceptions the label must clearly state

#### This package for households without young children

or or if the package is small

#### Package not child resistant

2. The prescribing physician or consumer may request that prescription medicines be put into ordinary packaging without safety features. Although some pharmacists may ask for a written statement from a purchaser before providing a conventional closure, this is not a requirement of the Federal law or the State law but for the pharmacist's own protection.

For those drugs packaged in containers which are intended by the manufacturer to be dispensed to the consumer in the original package, the obligation to provide special packaging rests with the manufacturer. (This does not, however, relieve the pharmacist of the obligation to inspect those packages which he receives, and, in absence of special packaging, to provide the same).

# Classified Ads

Classified ads are a complimentary service for members.

(send replies addressed: ad no. \_\_\_\_\_, M.Ph.A., 650 West Lombard St., Baltimore, Md. 21201)

#### PHARMACIST WANTED

Permanent, part time, 30 to 40 hours a week, evenings and Saturdays. Contact Mr. Powell, Powell Pharmacy, Columbia, Maryland, 997-1600.

#### POSITION WANTED

Competent, energetic pharmacist with managerial experience looking for full time position — registered in Maryland. Herbert Cook — 484-5099.

Wanted, full time position preferably in Landover, Md. area. References available. Joseph F. Gindlesberger, 3122 75th Ave., Apt. #1, Landover, Md. 20785.

#### Classified Ad #23

Pharmacist with background in hospital and community pharmacy wants 15 to 20 hours per week. Prefer Tuesday and Thursday afternoon or evening. Must be flexible to fit in with other work.

#### FOR RENT

Store for Rent. Pikesville Plaza Bldg., 600 Reisterstown Rd., Baltimore. 1000 sq. ft. in a Medical office bldg. 486-3900.





Feb. 12 (Sun.) — BMPA Annual Installation Dinner Dance, Blue Crest

Feb. 23 (Thurs.) — BMPA Meeting — Medicaid Survey & Drug Product Selection, Ramada Inn

Mar. 5 (Sun.) — MPhA Swain Seminar "Geropharmacy & Geriatric Medicine"

Mar. 12 (Sun.) — Alumni Association Dinner Meeting, Martin's West

Mar. 19 (Sun.) — AZO Fraternity Dinner Meeting April 13 (Thurs.) — MPhA/MSHP Joint Meeting, Kelly Memorial Building

May 13-18 — APhA Convention — Montreal

June 18-22 — MPhA Convention — Carousel Hotel, Ocean City

# Support National Poison Prevention Week-March 19-25, 1978



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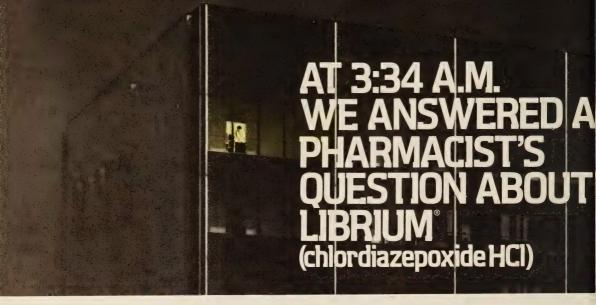
# **Epilepsy, Epileptics and Anticonvulsants**

- Raymond L. Spassil, M.S.
- Peter P. Lamy, Ph.D., F.C.P.

# A.Ph.A. Policy Positions on Pharmacy Issues

# Histamine H-2 Receptor Antagonists — Climetidine

- Robert Feroli, Jr., Pharm.D. Student



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**Contraindications:** Patients with known hypersensitivity to the drug.

Warnings: Warn patients that mental and/or physical abilities required for tasks such as

driving or operating machinery may be impaired, as may be mental alertness in children, and that concomitant use with alcohol or CNS depressants may have an additive effect. Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions), following discontinuation of the drug and similar to those seen with barbiturates, have been reported.

Usage in Pregnancy: Use of minor tranquilizers during first trimester

should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six. Though generally not recommended, if combination therapy with other psychotropics



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eems indicated, carefully consider individual harmacologic effects, particularly in use of totentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautors in presence of impaired renal or heatic function. Paradoxical reactions (e.g., xocitement, stimulation and acute rage) have been reported in psychiatric patients and hyperactive aggressive children. Employ isual precautions in treatment of arxiety tates with evidence of impending depression; suicidal tendencies may be present and infortective measures necessary. Variable effects on blood coagulation have been resorted very rarely in patients receiving the large and oral anticoagulants; causal relation-

ship has not been established clinically.

Adverse Reactions: Drowsiness, ataxia and confusion may occur, especially in the elederly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction; changes in EEG patterns (low-voltage fast activity) may appear during and after treatment; blood dyscrasias (includ-

ing agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making periodic blood counts and liver function tests advisable during protracted therapy. Supplied: Librium® Capsules containing 5 mg, 10 mg or 25 mg chlordiazepoxide HCl. Libritabs® Tablets containing 5 mg, 10 mg or 25 mg chlordiazepoxide.



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**MARCH 1978** 

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NO. 3

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cephalosporin, or other allergies before treatment. If an allergic reaction occurs, discontinue the drugand treat with the usual agents (e.g., epinephrine or other pressor amines, antihistamines, or corticosteroids).

Precautions: Use with caution in individuals with histories of significant allergies and/or asthma. Do not rely on oral administration in patients with severe illness, nausea, vomiting, gastric dilatation, cardiospasm, or intestinal hypermotility. Occasional patients will not absorb therapeutic amounts given orally. In streptococcal infections, treat until the organism is eliminated (minimum of ten days). With prolonged use, nonsusceptible organisms, including fungi, may overgrow; treat superinfection appropriately.

Adverse Reactions: Hypersensitivity, including fatal anaphylaxis. Nausea, vomiting, epigastric distress, diarrhea, and black, hairy tongue. Skin eruptions, urticaria, reactions resembling serum sickness (including chills, edema, arthralgia, prostration), laryngeal edema, fever, and eosinophilia. Infrequent hemolytic anemia, leukopenia, thrombocytopenia, neuropathy, and nephropathy, usually with high doses of parenteral penicillin. [102178] \*Equivalent to penicillin V.

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# Our Message Must Be Heard

The United Mine Workers recent strike has caused hardship and expense to much of the nation. Their voice was heard in all the media and the results are apparent. Though we may not be sympathetic with this type of speaking out, we must surely find a way of having our message heard. We can no longer continue to have third-party prescription payment programs steal our profits and become our silent partners. It is time to speak out to the administrators of Union Plans and at the same time to express our concerns to their members. Most of them have no idea of the extent to which pharmacy subsidizes the health care of their families.

As for the Medicaid program, it is now insult added to injury. More MAC prices for drugs and more and more harassment from the offices of Medicaid. Constant problems in Maryland Medicaid are arising and no real cooperation from its officials. Let us stop listening to the lip-service being paid to our cause and demand fair and equitable reimbursement for services rendered. When the cost survey is complete we will have the ammunition to fight our battle in court. If you are called upon to participate, give accurate and honest answers and full cooperation to the survey staff. We will not sit idly by while the government inflicts its confiscatory practices upon us. It may also help to contact your state legislators to keep them apprised of the plight of Maryland Pharmacist voters.

MARCH, 1978

### **Epilepsy, Epileptics and Anticonvulsants**

Raymond L. Spassil, M.S. and Peter P. Lamy, Ph.D., F.C.P.

#### Abstract

The effectiveness of anticonvulsant drug therapy depends on a number of factors. Among these are age of onset of the first seizure, cause or causes of the seizures, type of seizures and initial treatment.

In addition to complete seizure control not being achieved due to the factors just mentioned, seizure control can also depend on a host of psychosocial problems which confront the patient, either self-imposed or imposed by society-at-large. The use of alcohol, concurrent use of other drugs, folate replacement in folate-deficient individuals and intercurrent illnesses may also jeopardize seizure control.

Presently, it is possible to utilize established therapeutic ranges of drug blood level concentrations to monitor the epileptic. In addition, blood levels can be used to reinforce patient instructions. Through the utilization of drug blood levels in these two manners, maximum seizure control can be attained.

#### **History of Epilepsy**

Probably no other human affliction remains so misunderstood, so clouded by misinformation and social prejudice, and so unsuccessfully managed as is epilepsy.(1).

As far back as 2080 B.C., there was mention of epilepsy(2). In 400 B.C., Hippocrates argues that epilepsy

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had a natural cause(3). The brain, he felt, was the seat of this disorder, being oversaturated with 'phlegm'; the symptoms of the epileptic attack being due to the 'phlegm' rushing into the blood vessels of the body(2).

Galen(3) believed that the disorder was due to an obstruction of the posterior ventricles of the brain by 'phlegm' or 'black bile'. In addition to epilepsy being an idiopathic disorder of the brain, Galen also felt that it may be due to sympathetic involvement of the brain resulting from a disorder in another part of the body(4).

Willis described those seizures associated with periodic disorders of sensation as temporal lobe epilepsy(5).

In the late 19th century, Jackson defined an epileptic seizure as being a state produced by a "sudden, violent, disorderly discharge of the brain cells" (6). Later, a type of seizure was given his name(5). Many prominent men have had epilepsy, among them were Julius Caesar, St. Paul and Vincent van Gogh(7).

#### Causes of Seizures

A seizure is a manifestation of disturbed brain function and can be produced in any individual upon exposure to stimuli which exceed a convulsive the shold(6). Fortunately, the brain cells of most individuals have an innate resistance to excessive stimuli(8).

The epileptic activity generated within an epileptogenic focus is difficult to explain. Tower(9) feels that an accumulation of free acetylcholine metabolism, due to a chronic defect in acetylcholine, plays an important role. This would render the membrane hyperexcitable, in addition to the membrane demonstrating excitability due to an increase influx of sodium and a depletion of intracellular potassium. It is also felt that the lack of, or the decrease in, gamma-amino-butryic acid (GABA), which is an inhibitory transmitter substance within the brain, is an important factor in the generation of seizure activity(10). Matsumoto and Marsan(11) feel that the membrane may be intrinsically unstable. This may be due to an abnormal increase in the ionic permeability of the neuron and a decreased threshold of the resting potential(12).

Epilepsies can be classified into two groups, idiopathic or symptomatic, based on the etiology of the specific epilepsy. Idiopathic epilepsy, also known as cryptogenic, essential or primary epilepsy, is that type of epilepsy for which no cause for the seizure can be identified(13). Boshes et. al. (14) state that cases of essential or idiopathic epilepsy are only those in which no assignable cause has been found. Heredity also appears to play an obvious role in idiopathic epilepsy(15). Although the neurological exam may appear normal, the electroencephalograph will display an altered brain wave pattern(16).

Symptomatic epilepsy can be traced to a specific cause(13). This type of epilepsy can be further divided into disorders associated directly with the brain and those disorders of the body secondarily affecting the brain. For example, tumors, head injury, encephalitis, meningitis or a rare disease present at birth, such as phenylketonuria, can directly affect the brain. Stokes-Adams attacks or hypoglycemia are conditions which affect the brain secondarily(5).

The age of onset for seizures can usually be related to a presumptive cause. For example, seizures occurring under 10 years of age are usually due to some type of birth injury or childhood disease which has left scars and adhesions on the brain(16). Between the ages of 10 and 20 years, idiopathic epilepsy is most often diagnosed, although trauma to the head cannot be excluded(17). Trauma can usually be expected as the cause for seizures between 20 and 35 years of age, whereas neoplasms are the prevalent cause for seizures in individuals between 35 and 55 years of age. The incidence of cerebral lesions due to arteriosclerosis is high in the 55 to 70 year old age group(18).

**Types of Seizures** 

In a recent survey of 2,000 epileptic patients(19), 59 percent were found to have generalized seizures, while one percent had pure partial seizures. The remaining 40



percent had mixed seizures, with psychomotor seizures being the most prominent. Control can be achieved in 50 to 60 percent of those patients with grand mal seizures, but only in 20 to 30 percent of those individuals with psychomotor seizures(20).

The International League Against Epilepsy has suggested a classification for epileptic seizures in order to facilitate the utilization of a common language among neurologists(15). The following is a brief summary of the proposed classification(21):

- 1. Partial Seizures (seizures beginning locally)
  - a. Elementary symptomatology (generally without impairment of consciousness)
- (1) Jacksonian seizures
  - b. Complex symptomatology (generally with impairment of consciousness)
    - (1) Psychomotor seizures
- 2. Generalized Seizures (bilaterally symmetrical and without local onset)
  - (1) Tonic-clonic seizures (grand mal)
  - (2) Absences (petit mal)
- 3. Unilateral Seizures
- 4. Unclassified Epileptic Seizures

Grand mal seizures are probably the best known of the generalized seizures. The grand mal seizure is comprised of two stages, the tonic and the clonic. The tonic stage consists of a rigid state of the muscles of the body whereas the clonic stage consists of very rapid, rhythmic contractions of the muscles. A very brief warning or 'aura' may precede the tonic stage of the seizure. Auras are usually sensory, psychic, or motor in nature and usually last less than one minute. After the aura, the patient will suddenly lose consciousness and the tonic stage of the seizure will commence, lasting about 10 to 20 seconds. The clonic stage usually lasts about 30 to 60 seconds(15). During this stage, injuries may frequently occur. The clonic stage is followed by complete muscular relaxation. The patient may fall into a deep sleep or recovery from the seizure may occur. A headache or confused state may affect some patients for a minute or two following the seizure(6). This entire sequence may last up to five minutes or longer(1).

Petit mal seizures, also classified as generalized seizures, are characterized by momentary lapses of consciousness(22). The patient will usually cease any ongoing activity and become unresponsive(15). There may

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be some eye involvement with minor movement of the upper extremities. This impairment of consciousness usually lasts about five to 30 seconds. Activity is resumed after this time, with the patient only being aware that some time has passed unaccountably(15). Petit mal seizures seem to occur more frequently during relaxation and drowsiness, and may occur from five to 100 times or more a day(23).

Psychomotor or temporal lobe seizures are usually manifested by mental, motor and sensory symptoms. Misperception of the environment is not uncommon, with objects appearing to be far away or unreal (jamais vu); or strange objects or persons appearing to be very familiar (deja vu)(19).

Psychomotor seizures are often accompanied by changes in behavior. These automatisms may be divided into purposeless or purposeful movements, both coordinated and uncoordinated(10). It is quite evident that uncoordinated, purposeless, automatic behavior represents the most primitive type and, therefore, would not be difficult to identify. The coordinate, purposeful activity of an individual, on the other hand, may escape detection because of such a high level of adaptation.

The Jacksonian seizure, which is classified as a partial seizure, usually begins with a clonic, rhythmic twitching of the fingers of one hand, one side of the face or one foot. The disorder then marches from the first area affected to other areas on the same side of the body. This correlates to those areas located on the anterior central gyrus portion of that particular side of the brain(17). For example, if the forearm was affected first, the arm, shoulder, thorax, abdomen, thigh, leg and foot would then be affected sequentially(19). Although the individual usually remains conscious through this type of seizure, the focus or origin of the seizure within the brain may spread to the other side of the brain, leading to a generalized seizure(5).

**Drug Therapy** 

Complete or partial control is not achieved in approximately 20 percent of the patients(20). Therapy should begin at the time of the first recognized epileptic manifestation, unless development of further seizures is unlikely(24).

#### Phenytoin

Phenytoin and other hydantoin anticonvulsants are used primarily to control generalized seizures(4,25). Petit mal seizures should not be treated with phenytoin, since hydantoin derivatives may increase the frequency of such seizures(26).

The main mode of action of phenytoin appears to be the prevention of seizure propagation discharge from the origin or focus of the over-stimulated brain cells(27). This probably occurs due to the stabilization of the neuronal membrance, thereby, in effect reducing the passive influx of soldium ions and/or by increasing the efficiency of the sodium pump, such that excess sodium accumulation intracellularly does not occur during stimulation(28,29).

Gastrointestinal absorption of phenytoin is almost complete (24). Absorption following an intramuscular injection, however, is erratic and unpredictable (30). Thus in changing the route of administration from the oral to intramuscular one, care must be exercised in order to maintain adequate blood levels (31). It has been recommended that the intramuscular dosage be one and one-half times the oral dose. At the time that intramuscular administration is discontinued and oral administration is begun, a dose equal to one-half the original dose should be administered for the same period of time the patient had been receiving intramuscular phenytoin (32).

Approximately 80 percent of an oral dose of phenytoin is bound to plasma proteins(33).

Phenytoin is metabolized in the liver and is excreted in the conjugated form into the bile(26). The chief end product of liver metabolism is 5-(p-hydroxyphenyl)-5-phenylhydantoin (HPPH)(24). Approximately 60 to 75 percent of the oral dose is recovered in the urine as HPPH conjugates(34). One percent of the drug appears to be excreted unchanged in the urine(35).

Side effects of the drug are dose related and can be correlated to blood levels. Some sedation occurs at 10 mcg./ml., nystagmus occurs at 20 mcg./ml., ataxia occurs at 30 mcg./ml. and somnolence occurs at 40 mcg./ml.(36). One side effect will continue as the blood level concentration increases, with other side effects becoming superimposed(37).

Adverse effects of phenytoin therapy, which are most prevalent, are hypertrophy of the gums, hirsutism, hypocalcemia and osteomalacia(24).

The usual adult dose of phenytoin is 300 mg. per day in divided doses(35). Once-a-day dosing may be implemented after a steady state has been achieved and gastrointestinal side effects have subsided(29). Phenytoin's half-life, after oral administration, is approximately 22 hours(38). Thus, drug blood levels should not be determined for at least five to 10 days after therapy has commenced, in order to allow for a steady state to be achieved(24).

Interactions between phenytoin and other drugs usually result in the alteration of phenytoin's blood level. Phenobarbital, for example, may increase, decrease, or have no effect on the blood level of phenytoin(39).

Isoniazid, coumarin anticoagulants, and disulfiram may interact with phenytoin causing an increased phenytoin blood level(40). The interaction of these drugs with phenytoin appear to be of more clinical significance than the interaction between phenytoin and phenobarbital(41). Other drugs which have been reported to elevate phenytoin drug blood levels are chloramphenicol, chlordiazepoxide, chlorpromazine, diazepam, estrogens, methylphenidate, and propoxyphene(42). Ethyl alcohol and folic acid replacement in folate deficient patients, may increase the metabolism of phenytoin, thus resulting in a decrease of phenytoin blood levels(41). Adverse effects on seizure control or clinically evident phenytoin toxicity due to interactions do not occur in most patients(43).

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#### Phenobarbital

Phenobarbital is used primarily in the treatment of generalized convulsive seizures and all forms of partial seizures (4,25), but is not the drug of choice for petit mal seizures (44).

The main mode of action of phenobarbital is the depression of multisynaptic pathways in the brain stem, as well as the spinal monosynaptic reflex arcs(45). This is probably accomplished by a reduction in the excitability of the entire nerve due to the blockage of sodium and potassium transport across the cell membrane(27). Phenobarbital also increases the threshold for electrical stimulation of the motor cortex by depressing the depolarizing effects of acetylcholine(45).

The absorption of an oral dose of phenobarbital is slow and varies between 70 and 100 percent(46). Fifty to 60 percent of phenobarbital is bound to plasma proteins(47).

Phenobarbital is metabolized by the liver to form p-hydroxyphenobarbital, an inactive metabolite(35). Approximately 80 percent of the drug is excreted in the urine in conjugated forms, the rest being excreted by the kidney unchanged(46).

Phenobarbital's side effects can be directly correlated with the drug's blood level. Drowsiness occurs at 20 mcg./ml., ataxia at 40 mcg./ml., and somnolence at 60 mcg./ml.(37). The drug may produce paradoxical excitement in both children and elderly patients(35).

The usual adult dosage of phenobarbital is 100 mg. to 200 mg. daily(35). This agent can be given once a day, preferably at bedtime, due to its three to four day half-life(48). Approximately three weeks should elapse between the onset of therapy and drug blood level determination(49).

Phenobarbital affects the metabolism of tricyclic antidepressants, corticosteroids, coumarin anticoagulants, and digitoxin(39). Phenobarbital may decrease griseofulvin blood levels by imparing its absorption, while monoamine oxidase inhibitors may inhibit the metabolism of phenobarbital(44). Central nervous system depressants, such as ethyl alcohol, should not be administered concurrently with phenobarbital(41).

#### Primidene

This anticonvulsant is used primarily in the management of psychomotor seizures(50).

The mode of action of primidone appears to be the same as phenobarbital(24).

Approximately 60 to 80 percent of an oral dose is absorbed from the gastrointestinal tract(35). Neither primidone nor its metabolite phenylethylmalondiamide (PEMA) is bound to plasma protein to any appreciable extent(51).

Primidone is metabolized by the liver into PEMA, phenobarbital and p-hydroxyphenobarbital. PEMA possesses weak anticonvulsant properties and is more toxic than the parent compound. Approximately 15 to 25 percent of the oral dose is excreted unchanged in the urine, with 15 to 25 percent of the oral dose being metabolized to phenobarbital and 50 to 70 percent being excreted in

the urine as PEMA(35).

Primidone frequently causes drowsiness, sedation, ataxia, vertigo, diplopia and nystagmus. Rashes, alopecia, edema of the eyelids and legs, leukopenia, eosinophilia and impotence also occur but usually subside when the drug is discontinued(35).

The initial dose of the drug is usually 250 mg. This is increased by 250 mg. at weekly intervals and administered in two to four divided doses, not to exceed two grams daily(44). Although the half-life of primidone is approximately 10 to 12 hours, drug blood levels should not be determined until three weeks after initial therapy or a change in dosage has occurred, as 15 to 25 percent of primidone is converted to phenobarbital(53).

The interaction between primidone and phenytoin is probably a significant one. Phenobarbital levels are higher when phenytoin is added to a regimen which consists only of primidone, as compared to the levels which occur when only primidone is being utilized. A possible contributing factor may be phenytoin-induced competitive inhibition of phenobarbital's metabolism(54).

#### Succinimides

These agents are used chiefly in petit mal. Ethosuximide is considered to be the drug of choice in controlling petit mal seizures, although good results have also been demonstrated in the management of grand mal, myoclonic and psychomotor seizures(26).

#### Benzodiazepines

Oral administration of diazepam has been used in the treatment of various types of seizures. However, long term administration leads to patient tolerance requiring progressive increases in dosage(29). Intravenous diazepam is now the treatment of choice in status epilepticus(55).

Clonazepam is being used for akinetic, myoclonic, and absence seizures. There is a loss of the drug's effect within three months of initial therapy in up to 30 percent of patients(56).

#### **Psychosocial Problems**

Most epileptics demonstrate various psychosocial problems. These problems usually result from the patient's denial of the disorder, a denial which appears to be based on the hope to escape social, economic and personal consequences of the disorder itself(57).

Depression is frequently encountered among epileptics, as they perceive a lack of acceptance by their peers and, not infrequently, by their families(18,58). The patient's social activities are restricted and recognition of this fact may lead to depression(22). Defensive and aggressive behavior is often ascribed to the epileptic patient(59). Denial of the disorder may be the result of fear of economic failure. The epileptic patient faces a constant battle to obtain and retain employment(13). It is very likely that the patient fails to list the disorder on employment applications for fear of discovery and dismissal due to falsification of employment applications(60).

The most important factor leading to psychosocial problems is self-denial of the disorder. Nonacceptance of the disorder may cause an individual to take physical risks(59). This denial is often expressed in drug defaulting, with the patient simply refusing to adhere to a prescribed drug regimen, thus limiting seizure control.

A feeling of low self-esteem may be displayed by the epileptic, due to the individual's awareness that a lack of control over bodily functions may occur at any time(6). A feeling of embarrassment may follow a seizure(61). The patient's ego is adversely affected, as a sense of security is absent. Low self-esteem may also originate from certain restrictions placed on a patient's life style. The necessity for self-administration of drugs, the prohibition of alcoholic beverages, and denial of the privilege to drive an automobile are only a few examples(60).

All these factors can act as precipitants of further seizures, thus negating the effect the patient hoped would be achieved by this denial.



#### Unemployment

The Federal Fair Employment Act prohibits discriminatory employment practices based on race, color, religion, sex, age, national origin and physical or mental disorders(62). While there is no definitive proof of unfair employment practices regarding the epileptic patient, it seems clear that acceptance of the epileptic into the job market is less than desirable.

There is still the unacknowledged fear of the potential employer that an epileptic employee may have a seizure at any time. Some employers are reluctant to hire epileptics thinking that other employees will become apprehensive, which in turn might affect the work routine(26).

There is also the employer's perception that a company's economic well-being depends to a large degree on public acceptance. This could be dramatically affected if the public at large feels a certain reluctance in dealing with epileptic employees.

Some employers have felt that there is an unusually high rate of absenteeism among epileptics. This theory was disproved by Lione(63), who found that 80 percent of the epileptics working in an oil refinery required sick leave an average or less than average amount of time.

Other employers are fearful that their premiums for workmen's compensation coverage will increase, based on the premise that epileptics suffer from accidents more frequently than do unimpaired employees(64). This theory was also disproved(26).

Somewhat nebulous but rather important factors still combine to produce an unemployment rate among epileptics which far exceeds national statistics. The latest available figures show an average unemployment rate of 25 percent in 1965 for the epileptic, when unemployment nationally was less than five percent(16).

#### Utilization of Blood Levels in Therapeutic Management

The monitoring of drug blood levels has added a new dimension to the practitioner's armamentarium. Clinical laboratories can now identify and quantitate the concentration of drugs found in the bloodstream(65). For example, blood levels for 18 anticonvulsants can now be measured(66).

There are various indications for monitoring drug blood levels. The following appear to be the most significant (67).

- At the onset of therapy, to determine whether or not satisfactory drug blood levels have been obtained
- 2. During the course of therapy:
  - a. if seizures are suddenly no longer controlled
  - b. if intercurrent illness develops
  - c. if anticonvulsant dosage is changed
  - d. if dosage of any other drug is changed
  - e. if symptoms occur which might be related to a specific anticonvulsant
  - f. if drug defaulting is suspected

It would seem quite feasible to determine drug blood levels at the outset of anticonvulsant drug therapy, since the results could serve as a future baseline reference for the physician demonstrating the drug blood level at which the patient's seizures ceased(67). Also, if seizures suddenly ceased to be controlled, drug blood level determination would be of benefit.

Intercurrent illness of the patient may affect anticonvulsant absorption, distribution and elimination. Cotter et al. (68) speculated that carbamazepine's absorption may be diminished in conditions of increased gastrointestinal motility. Plasma protein binding of phenytoin may be diminished in renal and hepatic disease. Thus, the therapeutic effects of phenytoin may occur at lower plasma phenytoin levels than usual(69,70). Since most anticonvulsants are eliminated chiefly by biotransformation in the liver, other drugs which compete for or induce hepatic drug metabolizing enzymes can alter anticonvulsant blood levels(71).

The changing of an anticonvulsant dosage will inevitably affect drug blood levels. Thus, for anticonvulsants with monoexponential kinetics, five half-lives should elapse before drug blood level are determined(67). Although phenytoin follows Michaelis-Menten kinetics more closely than first order kinetics(72), the five times half-life rule (i.e., five half-lives should elapse in order to attain a steady state) can be utilized for this agent.

Frequently, epileptic patients also receive drugs for the management of other diseases or disorders. The alteration of another drug dosage, while maintaining a constant anticonvulsant dose, and its effect on the anticonvulsant blood level, is not well understood. It would be difficult to speculate as to when the anticonvulsant blood level would again become steady, should the second drug alter the distribution, metabolism or excretion of the anticonvulsant(67).

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Anticonvulsant drug blood level needed to control the most common forms of epilepsy in most patients, without producing side effects are now known(37). Through the utilization of these 'therapeutic ranges', control of the patient's seizures can be maximized(73).

Probably the most common reason for subtherapeutic drug blood levels is poor patient compliance(74-76). Non-compliance of patients on chronic anticonvulsant therapy has been stressed by various investigators (77,78), with the incidence among ambulatory populations ranging from 25 to 75 percent depending upon the criteria used for patient selection(79). L'und et al. (80) found that frequent consultation and determination of phenytoin blood levels, in conjunction with informing the patients of their blood levels and emphasizing the importance of compliance, raised their blood levels into the therapeutic range. Kutt and McDowell(81) found that a large portion of ambulatory patients who were 'refractory' to phenytoin were so only because of erratic intake of the drug. After hospitalization and close supervision of drug intake, blood levels were found to be commensurate with intake. Thus, it seems apparent that blood levels can also be utilized as an instrument to attain better patient compliance.

As one can see, many factors must be considered in the management of the epileptic. However, maximum seizure control can best be attained through the utilization of drug blood levels in conjunction with good patient compliance.

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Continued on page 17



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### callendar



Mar. 2 — MPhA Board Meeting

Mar. 5 — Swain Seminar — "Geropharmacy and Geriatric Medicine"

Mar. 12 — Alumni Association — Oyster Roast

Mar. 19 — AZO Joint Dinner Meeting

Apr. 13 — MPhA/MSHP Joint Meeting

**Apr. 16** — AZO — Berman Memorial Pharmacy Seminar

Apr. 20 — MPhA Spring Regional

May 13-18 — APhA Convention — Montreal

June 1 — Alumni Association Graduation Banquet

June 16-18 — MSHP Annual Pharmacy Seminar —

Williamsburg, Virginia

June 18-22 — MPhA Convention — Carousel Hotel, Ocean City

# DUES



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# **APhA Policy Positions On Pharmacy Issues**

1.\* NATIONAL HEALTH INSURANCE. The Association endorses the concept-of National Health Insurance as one means by which the costs of health care may be controlled and rational order brought to the health care system.

The Association recommends the following as general policy guidelines:

- a. a National Health Insurance plan must recognize that high quality health care is a right of every citizen regardless of his economic or social status
- **b.** a National Health Insurance plan must, as a point of departure, provide a health care delivery system which will correct the present inadequacies in the delivery of health care
- a National Health Insurance plan must allow for maximum utilization of pharmacist manpower in health care roles
- d. group practices established under National Health Insurance must permit pharmacists' participation on an equitable basis and not merely as employees of physician-controlled groups
- a National Health Insurance plan should to the extent feasible, utilize existing community pharmacies as health care facilities
- f. a National Health Insurance plan should provide for comprehensive pharmaceutical service
- g. a National Health Insurance pharmaceutical service benefit must include acceptable methods for ensuring equitable reimbursement to pharmacists for products and services which are to be provided under the program h. reimbursement to pharmacists for dispensed medication and devices under National Health Insurance should be based on professional fees for professional services plus reimbursement for the actual cost of any drug product or service provided
- i. a National Health Insurance pharmaceutical service benefit must optimize administrative efficiency and minimize administrative costs.

### 2.\* MAC/EAC

a. The Association supports only those government operated or financed third party prescription programs which ensure that participating pharmacists receive individualized, equitable compensation for professional services and reimbursement for products provided under the program.

- b. The Association regards "equitable compensation" under any government-operated or financed third party prescription program as requiring payments equivalent to a participating pharmacist's prevailing charges to the self-paying public for comparable services and products plus additional documented direct and indirect costs which are generated by participation in the program.
- c. The Association supports those government-operated or financed third party prescription programs which base compensation for professional services on professional fees and reimbursement for products provided on actual cost, with the provision of a specific exception to this policy in those instances when equity in professional compensation cannot otherwise be attained.
- 3. STATE VOLUME PURCHASE PLANS. The Association does not support the concept of state centralized purchasing schemes, which would adversely affect patient care quality and seriously disrupt the drug distribution system. States would do better to optimize administrative efficiency and minimize administrative costs in their effort to cut state health care expenditures.
- 4.\* DIRECT PRICE LIMITATIONS. The Association urges state Medicaid officials to permit pharmacists to select and dispense a quality drug product, and permit the use of any available drug product when unique medical circumstances require. The Association opposes any state efforts to impose direct price reimbursement or large size cost reimbursement on the pharmacist.
- 5.\* PRODUCT SELECTION. APhA supports state laws which permit pharmacists to select the source of supply of drugs which they dispense. The Association wishes to emphasize the pharmacist's professional responsibility for determining, on the basis of available evidence including professional literature, clinical studies, drug recalls, manufacturer reputation and other pertinent factors, that the drug products he dispenses are therapeutically effective.
- 6. PATENTS AND TRADEMARKS. The Association believes that patent and trademark protection for health care products should remain totally consistent with that provided for any class of products, and that the free enterprise and patent systems are valuable incentives for privately funded research and development.
- 7.\* PRODUCT LABELING. The Association has adopted the following guidelines in regard to drug identification codes:
- a. legislation should provide that the name of the manufacturer of the final dosage form be made part of the approved labeling of all prescription drug products

<sup>\*</sup>Issues identified by asterisks are official policy of the American Pharmaceutical Association as adopted by our House of Delegates.

- b. the code authorized by the legislation should be relevant to professional practice in identifying individual commercial packages and administered doses
- c. drugs when dispensed on prescription generally should be exempt from the requirement that the prescription label bear the code
- **d.** pharmacists, when performing professional duties in providing medication on prescription orders, should be exempt from the packager and labeler provisions.
- 8. WARRANTY AND PRODUCT LIABILITY. The Association believes that manufacturers should provide comprehensive product liability coverage for their products.
- 9.\* DISCRIMINATORY PRICING. The Association supports the equality of opportunity concept and urges the pharmaceutical manufacturing industry to eliminate policies and practices which establish de facto discrimination in cost prices, package sizes and services available in the same or interacting markets. The Association believes that the problem is sufficiently acute to justify recourse to the public at large and the legislature if necessary.
- 10.\* NET PRICING. The Association recommends that the pharmaceutical industry adopt a "net pricing" system which would eliminate hidden discounts, free goods and other subtle economic devices. We believe that a drug product has a value and that value ought to be reflected in its price. The Association firmly believes that the value of the drug product does not vary with the environment from which it is dispensed or in which it is administered.
- 11. RESALE PRICES. APhA highly recommends that manufacturers and wholesalers should be required to include in their drug advertising explicit selling price information. Pharmacists have historically been unable to purchase drug products at uniform prices, and variations in dispensed prescription charges can be largely attributed to this fact. Therefore the Association strongly supports efforts to require both manufacturers and wholesalers to publish price information for pharmacists.
- 12.\* EXPIRATION DATING. The Association recommends that manufacturers of prescription and non-prescription drugs include on the package label adequate information regarding storage requirements and a date after which the product should not be used. To simplify product location and recall at all levels of distribution, expiration dates should fall in the months of January or July, when feasible (e.g.: long-dated products). The Association also recommends that all practitioners and wholesalers provide controlled room temperature storage conditions as defined in the official compendia to adequately store drug products.
- 13.\* RECALLS AND RETURNS. The Association recommends that manufacturers adopt return goods policies that allow the return of drug products even if the expiration date has not yet occurred.

The Association recommends with regard to recalls: **a.** a standard recall form be instituted for all recalls

- b. the information contained on this form include the manufacturer and distributor of the drug, the full reason for recall, the control numbers of the lots being recalled and a reproduction of the label of the product
- c. all pharmacists receive a copy of the recall
- d. criteria be established for the depth of recall
- 14.\* AUTOMATED ORDER ENTRY/COMPUTER-IZED PATIENT AND PRESCRIPTION RECORDS. The Association supports regulatory changes at the national and state levels that would provide for computerized patient and prescription records as an alternative to manually prepared record systems. The Association also supports electronic data processing as a vehicle to keep down the administrative costs associated with pharmaceutical service.
- 15.\* CODE AND SYMBOL USAGE. The Association believes that the existing National Drug Code system should be revised to provide for a uniform identification number for the same drug entity, dosage form, strength and quantity in addition to a manufacturer's identification number.
- 16. PATIENT PACKAGE INSERTS. APhA believes that FDA should provide for patient package inserts as part of a well-designed, total program oriented both to the health professions and to the public and that, in a proper program, the pharmacist is the proper source of distribution to the patient. However, APhA is not in favor of mandated patient package inserts, since a pharmacist who disregards the prescribing physician's instructions to withhold from a particular patient the labeling mandated risks the breach of his relationship with that prescriber, and a mandated program disrupts the patient-pharmacist relationship so that the pharmacist's ability to perform important professional functions will be severely impaired.
- 17.\* SAMPLING. The Association believes that manufacturers' drug sampling, as now practiced, is the source of much waste, ill will and drug diversion, and that associated hazards of uncontrolled storage conditions, the difficulty of enacting drug recalls, drug diversion and the lack of monitoring dated drugs are of particular concern to the pharmacist. The Association therefore recommends that pharmaceutical manufacturers phase out their systems of traditional physician sampling.
- 18. LICENSING OF SALES REPRESENTATIVES. The APhA opposes legislative and/or regulatory efforts that would license sales representatives of manufacturers or wholesalers. The Association believes that the manufacturers and wholesalers can adequately train and supervise detailmen, and that there is presently no need to create another licensing scheme to protect the public health.
- 19.\* POLYGRAPHS. The Association policy on polygraph testing is:
- **a.** Polygraph tests should not be used as a means of pre-employment screening in pharmacies.
- **b.** Polygraph tests should not be used in pharmacies for routine "security" checking of employees.
- **c.** Polygraph tests should not be used in pharmacies in the course of investigations for cause.

MARCH, 1978 21

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### 1978 BMPA BANQUET

On February 12, 1978, the Annual BMPA Banquet was held at the Blue Crest North on Reisterstown Road in Pikesville. Approximately 300 pharmacists, family and friends enjoyed the evening with dancing provided by the George Owens Band. Over 20 state legislators were also the special guests of the Association.





Stanley Yaffe (left) receives the Past President's plaque from recently installed President Milton Sappe (right).

Banquet Grand Marshal Charles Spigelmire (right) presents a special appreciation award to Mrs. Sonia Yaffe while Toastmaster Samuel Lichter looks on.

Hors d'oeuvres and cocktails were served to the large crowd prior to the start of the banquet.

Photo courtesy of Paramount Photo Service



Banquet Ticket Chairman Joseph Loetell and his wife Millie prepare for the evening's festivitites at the Blue Crest.



C. Allen Turner (left) receives the award designating him the BMPA Honorary President from David Banta (right), BMPA Executive Director.



We think there's a lot in common between your experience and ours. It's not easy to come by ... and it's not easy to replace. The training you went through, the service you've given, knowing the nature of the medications you dispense—these are important factors in your experience.





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The quality research that we contributed to the development of HydroDIURIL, the quality control that has marked its many years of production—this, too, is the kind of experience we believe you can appreciate. When it comes to HydroDIURIL, we hope you will make no substitutions for the experience that can have no substitute.

Contraindications: Anuria; hypersensitivity to this or other sulfonamide-derived drugs Warnings: Use with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. Cumulative effects may develop in patients with impaired renal function. Use with caution in patients with impaired repatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. May add to or potentiate action of other antihypertensive drugs: potentiation occurs with ganglionic or peripheral adrenergic blocking drugs. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possibility of exacerbation or activation of systemic lugus erythematosus has been reported. Lithium generally should not be given with diuretic because they reduce its renal clearance and add a high risk of lithium toxicity. Read circulars for lithium preparations before use of such concomitant therapy. Use in Pregnancy: Thiazides cross placental barrier and appear in cord blood; in pregnancy, weigh anticipated benefit against possible hazards to fetus, including fetal or neonatal jaundice, thrombocytopenia and possibly other adverse reactions that have occurred in adults.

Nursing Mothers: Thiazides appear in breast milk; if use of drug is deemed essential, patient should stop nursing.

Precautions: Perform periodic determination of serum electrolytes to detect possible electrolyte imbalance. Observe all patients for clinical signs of fluid or electrolyte imbalance, namely, hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs, irrespective of cause, are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting. Hypokalemia may develop, especially with brisk diuresis, in severe cirrhosis, with concomitant corticosteroid or ACTH therapy, or with inadequate oral electrolyte intake. Hypokalemia can sensitize or exaggerate response of heart to toxic effects of digitalis (e.g., increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements, such as foods with a high potassium content. Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver disease or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt except in rare instances when the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank goul may be precipitated in certain patients. Insulin requirements in diabetic patients may be increased, decreased, or unchanged; latent diabetes mellitus may become manifest. Thiazides may increase responsiveness to tubocurarine. Antihypertensive effects of the drug may be enhanced in postsympathectomy patients. May decrease arterial responsiveness to norepinephrine; this diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use, If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. Pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged therapy; thiazides should be discontinued before testing for parathyroid function.

Adverse Reactions: Gastrointestinal System—Anorexia; gastric irritation; nausea; vomiting; cramping; diarrhea; constipation; jaundice (intrahepatic cholestatic jaundice); pancreatitis; sialadenitis.

Central Nervous System — Dizziness; vertigo; paresthesias; headache; xanthopsia. Hematologic — Leukopenia; agranulocytosis; thrombocytopenia; aplastic anemia. Cardiovascular — Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or narcotics).

Hypersensitivity—Purpura; photosensitivity; rash; urticaria; necrotizing angiitis (vasculitis) (cutaneous vasculitis); lever; respiratory distress including pneumonitis; anaphylactic reactions.

Other—Hyperglycemia; glycosuria; hyperuricemia; muscle spasm; weakness; restlessness; transient blurred vision.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

Note: When used with other antihypertensive drugs, careful observations for changes in blood pressure must be made, especially during initial therapy. Dosage of other antihypertensive agents must be reduced by at least 50 percent as soon as this drug is added to the regimen. As blood pressure falls under the potentiating effect of this agent, further reduction in dosage, or even discontinuation, of other antihypertensive drugs may be necessary.

How Supplied: Tablets containing 25 mg hydrochlorothiazide each in bottles of 100 and 1000 and single-unit packages of 100; Tablets containing 50 mg hydrochlorothiazide each in bottles of 100, 1000, and 5000 and single-unit packages of 100; Tablets containing 100 mg hydrochlorothiazide each in bottles of 100. For more detailed information, consult your MSD representative or see full prescribing information. Merck Sharp & Dohme, Division of Merck & Co., INC., West Point, Pa. 19486

### In hypertension

TABLETS: 25 mg, 50 mg, and 100 mg

# Hydrochlorothiazide | MSD)

### **Drug Product Problem Report**

The case studies presented below are intended to serve as examples of the kinds of action that may be taken through the Drug Product Problem Reporting Program. While these results are from actual reports received, they are included for general illustrative purposes only. It is hoped that these examples will indicate to the pharmacist reader some of the areas where he or she may want to be alert. No reflection on any specific manufacturer, distributor, pharmacist, or product is intended or should be inferred from the case studies.

### No Anesthesia with Lidocaine HC1/Epinephrine

A hospital pharmacist in Wisconsin reported that one lot of lidocaine hydrochloride with epinephrine injection produced no anesthesia and no hemostasis. When FDA asked the manufacturer about it, the firm discovered during review of its records that a total of eleven recently expired lots of lidocaine with epinephrine of differing strengths showed degradation of the epinephrine to an extent substantially below labeled strength. The company began screening all of these strengths of lidocaine with epinephrine. This showed eight lots bearing unexpired expiration dates to be sub-potent. All of the affected lots were recalled by the firm.

#### Black Sediment Caused by Cold Weather

Investigation of an Arizona pharmacist's report that black particles had been found floating in the bottom of an oral rinse containing sodium fluoride revealed that the lot had been frozen in transit. The firm explained to the reporting pharmacist that the sediment was apparently due to an irreversible precipitation of red dye that results from exposure to extremely cold temperatures. The company said future shipments of this formulation would be protected during freezing weather, and that it is exploring alternative formulations that can withstand freezing.

### **Company Modifies its Formulation**

Responding to a Texas hospital pharmacist's report of "sticking" and "excessive powder," the manufacturer of pseudoephedrine hydrochloride 60-mg tablets examined a file sample, found them to be "slightly more brittle than desirable," and had its development laboratory modify the formulation to obtain a "slightly less

brittle and harder" tablet. In notifying the pharmacist of these actions, the firm stated, "Professional observation and reporting is an invaluable adjunct to our control system and its importance as a check on our control efforts cannot be over-emphasized."

#### Missing Control Dropper Tips

This case was reported by a Michigan pharmacist, one of whose patients noticed, when she broke the seal and tried to use the eye drops, that the control dropper tip was missing from the container. There were two containers involved in the purchase, and neither contained a dropper tip. The company alerted its engineering department, which had the filling equipment checked. In addition, the firm later informed the pharmacist, it began a system of on-line inspections to prevent another such occurrence.

### Bronchodilator Closures Changed After Pharmacists' Reports

Numerous reports about the presence of particulate matter in a bronchodilator solution used in inhalation therapy were received through the Drug Product Problem Reporting Program from pharmacists across the nation during 1976 and 1977. Three FDA inspections at the manufacturer's plant ultimately revealed that the particulate matter came from a new cap/liner system which the company was not controlling adequately. As a result of the reports and FDA's findings, the company discontinued the new cap/liner system and converted to a bakelite closure system. Meanwhile, it intends to conduct identity testing of the liner material used in the other system.

### Market Withdrawal

"Rectal applicator does not fit on tube of ointment" was the complaint of a community pharmacist from Illinois. The lot number involved was voluntarily recalled by the manufacturer from all accounts to which this hemorrhoidal product had been distributed.

#### **Gross Nuclear Contamination of Cartons**

A nuclear pharmacist in California reported continuing problems with gross contamination on the interior of the shipping cartons for an I-131 oral solution and 99Mo-99mTc generator. Since the contamination in-

volved a long-lived radiopharmaceutical, it created trash disposal problems. The pharmacist also reported that although he had been assured by the manufacturer that the problem would be "alleviated," no noticeable improvements had occurred. An FDA inspection at the company's plant indicated that the contamination came from the filling and sealing equipment. The firm is now monitoring the production equipment during manufacture of these iodine sources, and a health physics representative is making daily checks of the production area to identify potential trouble spots. Concerning the 99Mo-99mTc generator, the manufacturer is placing them on sheets of disposable paper to insulate them from possible contamination; in addition, it has instructed assembly line personnel on proper handling techniques to insure that generators are not contaminated, and it has added to the line an operator whose job it is to wipe off every generator.

### Label Misprint Leads to Recall

A Kentucky hospital pharmacist's report pointed out a discrepancy in labeling: "Drug is labeled as rauwolfia serpentina 100 gm. The patient identification portion of the package states 100 mg." The repacker/distributor recalled this product in unit-dose packaging.

### "Black Particles" from Clean Bottles

The manufacturer of an anticholinergic/antispasmodic elixir identified the "black particles" reported by a New Jersey hospital pharmacist as "rust," which can enter bottles as they pass through the drying ovens at the glass factory. The elixir's manufacturer adjusted the air cleaner that removes foreign particles from bottles prior to filling, and added an inspector to examine each bottle just before it is filled. The company also asked its packaging department engineer to investigate further corrective measures, and contacted the bottle supplier so that it could take steps to eliminate the "rust" problem.

### Recall Because of Hypotensive Reactions to Plasma

A pump technician and an anesthesiologist in California noted that thoracic surgery patients developed marked hypotension when plasma protein fraction was administered to them. They discussed it with the hospital pharmacist, whose report paralleled another from an Indiana hospital pharmacist. The company concerned issued a "stop use" letter — Class I recall.

### Contraindicated Products' Names Were Too Similar

A state pharmaceutical association executive reported the concern of several of his members over the marketing of two drug products under similar brand names. He wrote that the members had found "the similarity of these brand names particularly disturbing since (one product) is a diuretic quite frequently used in hypertension, while the second (a decongestant) is specifically contraindicated in that disease state." The manufacturer of the second, more recently marked decongestant product agreed to alter its name.

### Report Prompted a Color Change for Safety

"Could be very hazardous" was the comment from a pharmacy supervisor at a hospital in New York State, regarding the similarities between single-dose vials of one company's atropine sulfate and sodium heparin injections. She commented further that the vials were "not only identical in size and color of cap, but the printed wording on the vials is almost the same color." The manufacturer agreed, and changed the color of the sodium heparin vial's flip-off cap to distinguish it from that of the atropine sulfate.

### Company Installs Electronic Sensor

As a result of a Texas hospital pharmacist's report of an unfilled foil packet of anti-infective vaginal tablets, the manufacturer has advised that it has installed an electronic sensor to detect automatically any unfilled packets and reject them prior to packaging and shipment.

### Capsule Variations Lead to Phenytoin Recall

Two separate reports from pharmacists in Illinois contributed to the recall of several lots of phenytoin sodium capsules by the manufacturer. Both pharmacists noted variations in size and weight of the capsules, and one had even performed a weight variation test on the capsules — he found that 20 filled capsules, chosen at random, varied from 164.6 mg to 229.2 mg, while the empty capsule shells varied only from 47.3 mg to 49.7 mg. (For a description of a simple in-pharmacy test for weight variations of capsules, see p. 670 of USP XIX). As a follow-up to these reports, an FDA investigation at the manufacturer's plant revealed that several lots of the product were manufactured under inadequate Good Manufacturing Practices and that they failed to comply with USP content uniformity requirements. The company recalled all of the lots involved.

### Three Recalls on Chloral Hydrate Follow pharmacists' Reports

A large number of reports from pharmacists concerning leaking capsules of chloral hydrate prompted FDA to issue an assignment to its district offices asking them to examine the manufacturer's stability data for this product. Three separate recalls have thus far resulted: (1) one repackaging company agreed to a recall on two lots of chloral hydrate capsules when it was informed of the leakage problem — the FDA follow-up investigation showed that the repackager had used a five-year expiration date without acceptable stability date, while the manufacturer recommends an 18-month expiration date; (2) another repackager recalled one lot, made by the same manufacturer as in the previous case, when examination showed that 4.5% of the capsules had leaked; (3) a third repackager recalled one lot - made by a different manufacturer — at the pharmacy level because the capsules were leaking at the seams.

## Histamine H-2 Receptor Antagonists — Cimetidine

by
Robert Feroli, Jr.
Pharm.D. Student
Division of Clinical Pharmacy,
University of Maryland School of Pharmacy

Histamine acts at two receptor sites designated as H-1 and H-2. Conventional antihistamines such as diphenhydramine and brompheniramine are H-1 blockers which are useful in conditions such as allergic rhinitis and pruritis.

In 1972, Black et al (1) introduced a group of H-2 receptor antagonists. The first of these compounds to be studied in humans was metiamide. This compound was a potent inhibitor of basal gastric secretion. Other actions included decreased gastric acid response to histamine, pentagastrin, insulin, and peptone meal (2). Metiamide was withdrawn after a small number of patients developed agranulocytosis (3). Bone marrow toxicity was not thought to be related to H-2 blockade, but rather to the thiourea moiety present in metiamide. This assumption was reasonable because other thiourea containing compounds, such as propylthiouracil, also induced agranulocytosis.

Cimetidine was developed and differed from metiamide in one respect, a cyanoguanidine group replaced the thiourea moiety. To date, cimetidine has not been shown to suppress bone marrow function.

#### Action

Henn et al (4) demonstrated that after 300 mg. of cimetidine was administered on an empty stomach, basal acid secretion was maintained near zero for five hours. Meal stimulated three-hour acid output was reduced by 67 percent.

Pounder and associates (5,6) found that when given on an empty stomach, cimetidine's onset of action was rapid with a relatively short duration of action. Administering cimetidine with food resulted in a slower onset and longer duration of action.

Nocturnal suppression of acid secretion by cimetidine was studied by Longstreth (7). He demonstrated that a dose of 300 or 400 mg. administered on an empty stomach at 11:00 p.m., would maintain gastric acid output near zero for seven hours.

#### Efficacy

A double blind multi-center trial (8) compared oral cimetidine and placebo in patients with duodenal or pyloric canal ulcers. Cimetidine, 300 mg., was administered to 34 patients immediately before meals and at bedtime. Placebo was administered to 33 patients in a similar manner. After six weeks there was a significantly higher rate of complete healing in the cimetidine group (82%), as compared to the placebo group (39%). Daytime pain and antacid use were also significantly reduced in patients treated with cimetidine.

In another double blind study (9), oral cimetidine in two dosage regimens was compared to placebo. Patients had either duodenal or prepyloric ulcers, verified by endoscopy. Cimetidine, 200 mg. or 300 mg., was administered with meals and at bedtime.

Results wer	e as f	ollo	ws:		Complete	Healing
						6 weeks
Cimetidine	200	mg.	q.i.d.	(15	pa-tients)	53%

86% Cimetidine 300 mg. q.i.d. (15 pa-tients) 80%

Placebo 35% q.i.d. (14 pa-tients)

here was also a significant decrease in nocturnal pair

15%

Again, there was also a significant decrease in nocturnal pain, daytime pain, and antacid use in the cimetidine groups.

Use of cimetidine in gastric ulcers remains unclear. Pounder (12) et al conducted an uncontrolled trial in which 10 patients with gastric ulcers were given either 200 mg. or 400 mg. of cimetidine four times a day for six weeks. Endoscopy at the end of six weeks showed that all ulcers had healed. The significance of this study is unknown due to the high percentage of gastric ulcers which heal spontaneously. Further studies will be necessary to determine the role of cimetidine in gastric ulcer therapy.

Patients suffering from Zollinger-Ellison Syndrome have demonstrated clinical improvement and decreased acid output when treated with either cimetidine (13) or metiamide (14).

#### Adverse Effects

Cimetidine has been reported to cause mild and transient diarrhea, muscular pain, dizziness, and rash (15). The incidence of these side effects is approximately one percent. Also, transient elevations of SGOT, SGPT, and serum creatinine have been reported without elevations in BUN. The significance of these findings is unknown.

Several cases of breast pain with gynecomastia have been reported (16). The gynecomastia may be due to cimetidine induced increases in serum prolactin activity (17).

It has been reported that cimetidine does not cause rebound hypersecretion after drug discontinuation (8,18), a decrease in pancreatic secretion (19), or an increase in lower esophogeal sphincter pressure (20).

#### **Pharmocokinetics**

Following oral administration, 70-80 percent of cimetidine is absorbed. Percentage of drug absorption is the same in the presence of food, however, absorption may be delayed and the duration of action increased (21). The absorption is not affected by co-administration with antacids (21).

Seventy percent of cimetidine is excreted unchanged in the urine after 24 hours. Approximately 20 percent is metabolized to compounds of unknown activity. The half-life of cimetidine is two hours with normal renal function, and 4-5 hours when creatinine clearance is less than 5 ml./min. (21).

#### Indications

- The short term treatment of duodenal ulcer (up to eight weeks).
- The treatment of pathological hypersecretory conditions (i.e., Zollinger-Ellison Syndrome, systemic mastocytosis, multiple endocrine adenomas).

#### Dosage and Administration

Duodenal Ulcer — The recommended adult oral dosage is 300 mg. four times a day with meals and at bedtime. Concomitant antacids should be given as needed for relief of pain. While healing with cimetidinemay occur during the first or second week of therapy, treatment should be continued for 4-6 weeks unless healing has been demonstrated by endoscopic examination.

Zollinger-Ellison Syndrome — Recommended adult oral dosage: 300 mg. four times a day with meals and at bedtime. Doses should be adjusted to individual patient needs, but should not exceed 2400 mg. per day.

Dosage in Renal Failure (21)

Serum Creatinine		Dose		
3.5	mg.%	300 mg.	q6h	
3.5-5.0	mg.%	300 mg.	q8j	
5.0	mg.%	300 mg.	q12-18h	

#### **Product Information**

Tradename: Tagamet

Manufacturer: Smith, Kline and French Laboratories Dosage Forms: Tablets — 300 mg. Injection — 300mg./2ml.

#### References:

**OPEN** 

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Maryland Poison Information Center University of Maryland School of Pharmacy 636 W. Lombard Street Baltimore, MD 21201



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FOR

Health Professionals

MARCH 22, 1978

11 a.m. - 2 p.m. 6 p.m. - 8 p.m.

In conjunction with National Poison Prevention Week March 19 - 25, 1978

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MPIC	MATERI	ALS OF	RDER	FORM
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		Qualitit
Poison Primers	\$2/100	
Poisonous Plant	t list \$2/100	
Telephone stick	kers \$1/100	
MR YUK stickers	s (12/sheet)	
0-100 sheets	s 15¢/sheet	
101-500 sheets	s 12¢/sheet	
501-1000 sheets	s 10¢/sheet	

Circle local or WATS number wanted on MR YUK stickers

Sample packet 1 free

Make checks payable to: Poison Prevention, and send them with this form to: Inc.

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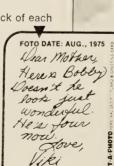
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### IRS Offers Tax Tips To Small Businesses

If you're in business for yourself — whether it be a restaurant, grocery store, laundry or barber shop — chances are you'll come face to face with most, if not all, of the following: insurance, bookkeeping, advertising, inventory and federal tax requirements.

And when it comes to federal tax requirements, one in particular touches virtually every business; that is, the requirement to withhold and deposit certain taxes periodically, such as income taxes and social security taxes from employee wages.

The law imposes severe penalties on taxpayers who willfully fail to take required actions; for example, when an employer withholds taxes from an employee's pay and knowingly fails to deposit it by the due date. A late deposit penalty of 5 percent of the undeposited tax may be assessed against this employer. Also, the law provides for a civil penalty equal to 100 percent of withheld income and social security taxes if the employer willfully fails to pay over such taxes to the government. This 100 percent penalty can be asserted against officers or employees of corporations who were personally responsible for the withholding tax and making payment to the government.

Just about every business has its ups and downs. The IRS is well aware of this and, therefore, continually advises businesspersons that if they see tax problems looming, the best time to deal with these problems is before they occur. For example, if you come to the IRS and tell them you're going to have trouble in making a required payroll tax deposit, they won't rush out to close you down. Instead they'll work with you to alleviate the problems before they could become fatal to your business.

Generally, withholding and deposit requirements vary depending on the size of the payroll and the past performance of the business in making deposits. The following are general guidelines:

— Employers having an undeposited cumulative liability of \$2,000 or more for withheld income taxes and social security taxes at the end of a quarter-month period (ending on the 7th, 15th, 22nd and last day of each month) are required to make a deposit within 3 banking days after the end of the quarter-month period.

— Employers having an undeposited liability of \$200 or more but less than \$2,000 in withheld income taxes and social security taxes at the end of any month (except the last month of the quarter) are required to make their deposit within 15 days after the end of the month.

Exact deposit dates for a particular year are listed in IRS Publication 509, "Tax Calendar and Check List for 1978," a free booklet which may be obtained by calling

the IRS toll-free tax information number.

Business taxpayers also should be aware of any excise taxes for which they may be liable. Federal excise taxes are imposed on certain sales, transactions, occupations and on the use of certain items. They are not based on the profits of a business activity.

Tax withholding/depositing and excise tax compliance are just two federal tax subjects that should be of interest to business owners. Some businesses also may be liable for the Federal Highway Use Tax, others for unemployment tax, even the Civil Aircraft Use Tax.

The rules governing some of these taxes can be found in the free IRS Publication 334, "Tax Guide for Small Business." This 192-page booklet contains a wealth of tax information and also lists most of the free IRS booklets that can help businesses at tax time.

Following through on a commitment to cut tax paperwork for businesses, the IRS has reduced reporting requirements on Form 941, "Employers Quarterly Federal Tax Return."

After January 1, 1978, you still will have to submit Form 941 but won't have to provide the detailed information required on Schedule A, Form 941. The form has been redesigned to include only the data needed by the IRS—total compensation paid, total income taxes withheld, FICA taxes withheld, and deposits made. Formerly, much of the quarterly information required on Schedule A, Form 941, was required by the Social Security Administration. Now, that information will be submitted annually on a re-styled Form W-2.

And keep in mind, IRS offices offer free assistance such as small business seminars which focus on the special tax rights and responsibilities of businesses as well as the importance of record-keeping and how good records can help you in your business. These seminars often are presented in cooperation with local or regional business organizations or universities.

For the individual planning to open a new place of business, the IRS can provide help long before the grand opening. IRS Publication 454, "Your Business Tax Kit," available from local IRS offices, is a folder containing most, if not all, of the forms and documents you'll need to file with the IRS. The kit also contains two especially useful items — a tax calendar of business tax deadlines for the year and IRS Publication 334, "Tax Guide for Small Business," the comprehensive reference full of valuable information. And in every state, business-persons can reach the IRS on toll-free phone numbers, twelve months a year, giving business owners easy access to the information, forms or publications they need.

31

### **COLBY PROCLAIMS WOMAN SUFFRAGE**

Signs Certificate of Ratification at His Home Without Women Witnesses.

MILITANTS VEXED AT PRIVACY.

Wanted Movies of Ceremony, **But Both Factions Are** 

WASHINGTON, Aug. 28 1920-



### Social Security Bill Is Signed Gives Pensions to Aged, Joi

Roosevelt Approves Message Intended to Benefit 30, Persons When States Adopt Cooperating Laws-He the Measure 'Cornerstone' of His Economic Progr

### SENATE APPROVES 18-YEAR OLD VOTE **INALL ELECTIONS**

Amendment to Constitution is Sent to House, Where Passage is Expected

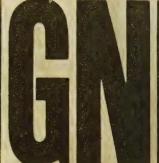
WASHINGTON, March 10. 1971-The Senate approved

WASHINGTON, Aug. The Social Security Bill, a broad program of unen insurance and old age and counted upon to ber 20,000,000 persons, becam day when it was signed dent Roosevelt in the pr those chiefly responsible ting it through Congres

Mr. Roosevelt cal



WASHINGTON, Jan. 27, 1973-"With the signing of the peace agreement in Paris today, and after redeiving a report from the



## the Dra Ends No

Secretary of the Army that



### NEW WORLD HOPE

President Hails 'Great Instrument of Peace.' Insists It Be Used

HISTORIC LANDMARK

Meeting Gives Standing **Ovation as Executive** Pictures Peace Gain

"If we fail to use it," he declared to the solemn final meeting of the delegates, 'we shall betray all of those who have died in order that we might meet here in freedom and safety to create it." If we seek to use it selfishly—for the advantage of any one nation or any small group of nations—we shall be equally guilty of that betrayal."

trayal."

Fervent Interpolation

The President, speaking in the auditorium of the War Memorial Opera House, built in memory of sons of the Golden Gate city who gave their lives in the first World. War, in which he himself served, war in which he himself served. var, in which he ministi served, eemed to give unconscious expression to the solemn feeling of the cession when, at the outset of his peech, he interpolated the words, alf a hope, half a prayer:

"Oh, what a great day this can in history?"

in history!".
Just before the plenary sess

# PATIENT PACKAGE INSERTS: A CONCEPT WHOSE TIME HAS COME?

The consumer's right to know is an ir reversible and desirable trend of the Seventies. It extends, and properly, to a patient's right to know more about his or her prescription medications. One way, gaining favor, is through patient package inserts. Wisely-prepared and properly distributed when medically indicated, they could markedly improve patient knowledge and drug therapy—laudable goals by anyone's standards.

The PMA endorses these goals and will work with government, the health professions and consumers to achieve them.

### The Advantages

The concept holds promise of benefits: better patient understanding of the product prescribed, better adherence to the treatment plan, and more awareness of possible side reactions.

Every doctor has had patients who fail to finish antibiotic regimens because they feel better. Some patients assume that if one tranquilizer or analgesic is good, two may be twice as good. Still others fail to report dizziness while on antihypertensive therapy—and so on.

Problems like these might arise less often if the patient received written information in addition to verbal instructions. Some studies suggest that patients are more receptive to such materials, and they more often understand the verbal instructions and follow them, when inserts are used.

### The Disadvantages

There are also some potential problems. Obviously, the inserts must be clearly phrased, without extraneous or complex detail. How much information is enough? How can it be kept current? Should all patients receive the same information? Should inserts be included with all drugs? Should only potential problems be listed or are patients better off with a "fair balance" presentation that describes usefulness as well as drawbacks?

These and similar questions require answers, since model inserts have yet to be properly developed and tested. Despite the need for these studies, the FDA is proceeding prematurely with inserts on selected products. We think the Congress is the only place where the matter can be given the proper legal status and direction, particularly since it represents a conceptual change in the legal, medical and social framework of the nation's prescription drug information system.

### The Solution

The PMA believes that carefully-devised pilot studies of various kinds of inserts are needed. They should be developed and implemented with full participation by doctors, pharmacists, consumers, communications experts and the drug industry. Such studies will provide reliable pathways to follow, so that inserts will be useful aids to medical practice.

And particularly we think that you should be closely involved in this debate and in these studies and decisions. Otherwise, people with less experience and qualifications may control the purposes, content and use of a tool with considerable promise for improved patient care. It could make a difference in your practice tomorrow, and more importantly, in the health of your patients.

### AING

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# Wow, have we got something for you...

MPhA Convention



Ocean City, Maryland June 18-22, 1978

Watch for More Details

### LETTERS



The practice of Pharmacy has been expanded with new privileges related to the lawful substitution of medications. Pharmacists have been placed into a position of professional responsibility related to the choice and cost of medications that is unparalleled in recent times. How we function in this new capacity may determine the future responsibilities that the public and the government will extend to us. My specific concern is the fees that are charged to patients who were taking brand named medication and are now taking generic medications. For instance, if a patient was charged a \$2.50 fee for a brand name product, why should the patient be charged a higher fee for a generic equivalent? Yet, I hear claims that since the patient is saving so much money why shouldn't the pharmacist make a higher fee? No one should forget that it is exorbitant prices charged by major pharmaceutical companies that has brought about generic dispensing. Exorbitant prices inflicted upon the public by physicians and hospitals has directed the scorn and disgust of an ever growing number of people. The lesson is there. It will be a short lived windfall profit if pharmacists make excessive profits at the expense of patients who, for the first time, have been won over to our side. For example, the \$70 purchase savings by the pharmacist between generic amitriptyline and the brand name product in 1000's is ample enough to not increase dispensing fees. The public will quickly see the motivations behind the requests for generic medication by pharmacists and transfer their disgust for the greed of pharmaceutical manufacturers to the greed of pharmacists.

M. Neal Jacobs

### **AZO Berman Seminar Set**

Kappa Chapter, Alpha Zeta Omega National Pharmaceutical Fraternity will hold its annual Frederic T. Berman Memorial Pharmacy Seminar on Sunday, April 16, 1978 at the Holiday Inn, Belmont (Social Security Exit #17) from 9:00 a.m. until 3:30 p.m.

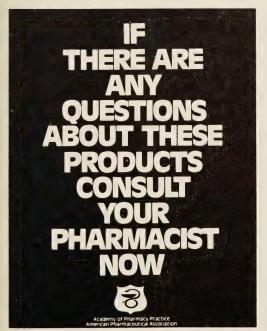
This seminar which is co-sponsored by the Continuing Education Division of the University of Maryland School of Pharmacy will present two areas of vital interest and importance to pharmacists and other health professionals. The program will offer a presentation by Arthur A. Serpick, M.D. on "Current Concepts in Cancer Chemotherapy."

Dr. Serpick is head of Hematology and Medical Oncology, University of Maryland Hospital and Assistant Professor of Medicine at the University of Maryland School of Medicine.

The second topic on the program is entitled "Pharmacy Manpower: Past, Present and Future." This subject will be discussed briefly from its various aspects by a panel composed of Ralph F. Shangraw, Ph.D., Professor and Chairman of the Department of Pharmacy, University of Maryland School of Pharmacy; Mr. Edward Spearbeck, Vice-President of Professional Services, Drug Fair, Inc.; and Dr. Lars Solander, Director, Office of Educational Research and Development, American Association of Colleges of Pharmacy.

The audience will be invited to participate in question and answer periods which will follow each presentation on the program.

Information concerning this seminar may be obtained by calling I. Dennis Klein, 484-3919; David Roffman, 528-7338 or Henry Seidman, 528-7589.



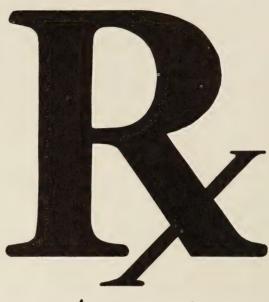
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directions on
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medication.



Academy of Pharmacy Practice

Vital Signs: These pharmacy counter displays are the first in a series called "Positive Signs for Patients," made available by the American Pharmaceutical Association's Academy of Pharmacy Practice. By encouraging questions about medication, the green and white, 8" x 10" plastic signs remind patrons of the pharmacists' vital clinical role. The APhA sells them for \$2.75 each or \$5.00 for both. The series is sponsored by Lederle Laboratories in conjunction with the Academy.



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APRIL, 1978
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NO. 4



### **Results of the Employment Conditions Survey**

### The FDA and Product Labeling

- An Interview with Commissioner Kennedy

### Pharmacist Liability under the New DPS Law

- Robert R. Michael, J.D.

### The Evolution of the Medicine Cabinet

- John C. Krantz, Jr., Ph.D.

### THE MARYLAND PHARMACIST

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# Remember, the summer of '77?

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And reminiscing about the summer of '77.

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### Pharmacy at the Crossroads

Much debate has been heard on the issue of one degree for pharmacists. Along with this is discussion of the role of pharmacy "aides" and whether a formal training program should be adopted for "technicians"?

We have heard the cry for National Health Insurance as we are in a battle over unfair reimbursement by the Third Party Administrators. MAC/EAC prices have been rammed down our throats.

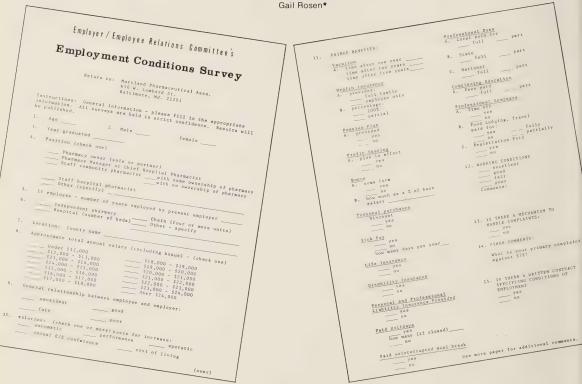
If we are to exist as professionals in the next century, we must take strong action now. All pharmacists will have to speak out to their patients, their congressional representatives, and other members of the health care team. We need pharmacists who are willing to be a part of the political process, either in office or working to help elect others favorable to the cause of pharmacy or at least willing to listen to our needs. Be Active! Stand for something positive or be brushed aside by the forces of change.

I appeal to every pharmacist to support the Associations and become politically informed and active.

Scharl Doar

# Results of the Employment Conditions Survey

by Russell LeSage\*
Ruth Sammel Blatt\*



Questionnaires were recently sent out to pharmacists in the state of Maryland by the MPhA Employer/ Employee Relations Committee in an attempt to illustrate employment conditions in various parts of the state as well as to compare some of the pharmacists' benefits and working conditions. There were 850 questionnaires sent out to which there were 245 replies, 28.8%. Of these 245 replies, 171 were either independent or chain pharmacists, 39 were from hospitals, 10 had jobs which could not be classified as either and 25 returns were not useable.

Of those responding, 95% were between the ages of 23-65, 13% of these were female. Pharmacists reported

having worked from 1 month to 30 years at their present job with 61% having their current job for less than 5 years.

### Salaries and Locations

Yearly salaries were elicited and broken down into community or hospital pharmacy and their locations. Of the 171 community pharmacists reporting, 74 of them owned or were partners of the pharmacy. These were not differentiated when tallying the results. There was no distinction made between chain or independent pharmacies. In the hospitals, directors and staff pharmacists were not differentiated when the results were tabulated. The biggest problem, however, in differentiating salaries was that the questionnaire did not include the number of hours each individual worked.

<sup>\*</sup> SAPhA members, University of Maryland School of Pharmacy

### SUMMARY IRRESPECTIVE OF LOCATION

Salary	Hospital		Community	
12	3		3	
13			1	
14			2 2	
15				
16	7		1	
17	10		3	
18	21	54%	3	
19	3		4	
20	13		7	
21	3		10	
22	6		8	
23	10	42%	10	81%
24	6		6	
24+	17		43	

These results would seem to indicate that community pharmacists make more money than hospital pharmacists. (Community 81% @ \$20,000, Hospital 42% @ \$20,000). No real conclusions can be drawn from this, however, because these statistics do not account for hours worked or position in pharmacy, i.e. staff, owner, director or manager.

#### Geographic regions

- 1. Ann Arundel, Baltimore City, Baltimore County
- 2. Prince George, Montgomery, D.C.
- 3. Allegheny, Washington, Garrett, Carroll
- 4. Talbot, St. Mary's, Calvert, Caroline, Worchester and Wicomico
- 5. Cecil. Kent. Harford
- 6. Frederick, Howard

#### S.

ALARY vs	. GEOGI	RAPHI	CAL A	REA		
Hospital sala	ary 1	2	3	4	5	6
12			1(3%)			
13						
14						
15						
16	2(7%)					
17	3(10%)					
18	6(21%)					
19	1(3%)					
20	3(10%)					1(3%)
21	1(3%)					
22	1(3%)	1(3%)				
23	2(10%)					
24	1(3%)					
24+	5(17%)					
Comm. salary						
12	4(2%)		1(1%)			
13	` ′			1(1%)		
14	3(2%)					
15	1(1%)		1(1%)			
16	2(1%)					
17	1(1%)	1(1%)				
18		3(2%)	2(1%)			
19		1(1%)	1(1%)	1(1%)	1(1%)	
20	4(2%)	3(2%)	1(1%)	1(1%)	1(1%)	

### FRINGE BENEFITS

Health Insurance						
CommunityY78%			125%			
full54%	part46%	full83%	part17%			
Pension plan						
CommunityY38%	N62%	Hospital	N100%			
Profit sharing						
CommunityY31%	N69%	Hospital	N100%			
Bonus						
CommunityY56%	N44%	HospitalY4%	N96%			
Personal purchasing dis	scount					
CommunityY94%	N6%	Hospital Y 71%	N29%			
Sick pay						
CommunityY77%	N23%	HospitalY100%				
Life Insurance						
CommunityY 64%	N36%	HospitalY100%				
Disability insurance						
Community Y 60%	N40%	HospitalY58%	N42%			
Personal and profession	nal liability					
CommunityY76%	N24%	HospitalY58%	N42%			
Paid holiday						
CommunityY82%	N18%	HospitalY100%				
Paid uninterrupted lunch						
Community Y 29%	N71%	HospitalY33%	N67%			

### PROFESSIONAL DUES

Community full Hospital		part15% 4%	none50% 67%
State Communityfull		part17% 4%	none58% 67%
National Communityfull	20% 29%	part6% 4%	none74% 67%
Continuing Education Community full		part13% 25%	none70% 17%

#### PROFESSIONAL SEMINARS

Α.	Community			
В.	Community		part3% 29%	none83% 4%
C.	Community			

### WORK CONDITIONS

Community		В.	38% 42%	C.	18% 17%	D.	6% 8%
Community		В.	29% 12%				
Community		В.	67% 83%				

#### Conclusion

1(1%)

1(1%)

1(1%)

3(2%)

The survey conducted by the Maryland Pharmaceutical Association can be a useful tool for both employer and employee pharmacists regardless of specialty of practice. Although several sections of the survey should be revised to exclude some superficial information and include other areas of interest, the results can be of value.

The large percentage of response to the questionnaire indicates that members of the Association are interested in this kind of survey data and it would appear that such a survey should be conducted by the Employer/Employee Relations Committee of the Association on a periodic basis in the future. As the survey becomes more refined, it may be possible for the results to be analyzed by computer for a more detailed comparison of this data.

22

23

24

10(6%)

2(1%)

8(5%)

4(2%)

3(2%)

8(5%)

3(2%)

3(2%)

33(21%) 19(12%) 8(5%)

1(1%)

2(1%)

2(1%)

2(1%)

2(1%)

1(1%)

1(1%)

4(2%)

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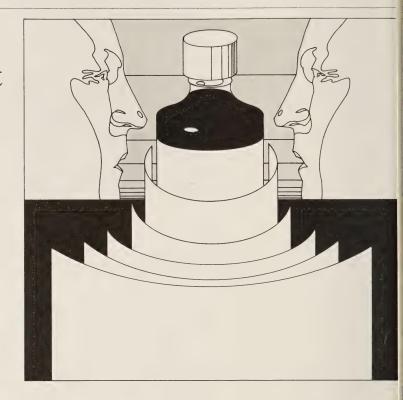


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# The FDA and Product Labeling



Reprinted from FDA Consumer February, 1978

S ince becoming Commissioner of Food and Drugs in April 1977, Dr. Donald Kennedy has emphasized the need for improved product labeling. He expects major FDA initiatives in labeling in the years ahead. In this interview with Wayne L. Pines, deputy assistant commissioner for public affairs, Dr. Kennedy explains why he believes labeling is a key to enlightened regulation, and the plans he has for FDA in this critical area.

Or. Kennedy, you've stressed the need for products to be adequately labeled. What is your philosophy about labeling?

A. I start from the premise that people are intelligent and rational, and inclined to act in their own best interest when presented with choices. Obviously, information is the key element in deciding among several options. The products regulated by FDA are marketed in such a way that labeling appears to be a uniquely effective means of communicating information to prospective purchasers. So I place strong emphasis on the need for

products to be labeled accurately and with balanced information. In my view this is one of FDA's most important responsibilities.

What is the Government's role in providing consumers accurate and honest product information?

A. I think FDA's role is to assure that industry provides full, fair, and accurate information on product labels, and advertises products in a way that is consistent with the label. The Government gets into the information providing business itself only where it finds serious inadequacies or

systemic defects in the efforts of manufacturers. Otherwise we in Government are regulators of what industry does, or stimulators encouraging industry to do a better job.

FDA's experience with Laetrile and saccharin indicates that many people want the Government to get out of the business of banning products, and merely make sure products are labeled adequately, and let people make up their own minds. How do you feel about this?

A. These controversies certainly have had some effect on my own thinking about labeling and product hazards. But they have not made me withdraw or step back from the need sometimes to regulate the availability of products as well as their labeling. I continue to believe in the basic soundness of the law that prohibits the addition of unsafe additives

to food, because in a complex universe like this you really can't ever hope to supply consumers with enough information about all products to enable them to exercise voluntary choices safely. And I don't believe we should ever permit the sale of unsafe or ineffective drugs merely by labeling them as unsafe or ineffective and letting the consumer decide for himself. The basic concept of our drug approval system is that drugs must be proved safe and effective; in other words, that's the point of departure for the labeling of drugs. But when it's possible to give people enough information about benefits and risks to make their own selections in the marketplace, that is certainly the best step to take.

Where do you draw the line between a product that is so hazardous that its availability should be restricted, and one that can be adequately labeled?

The line doesn't involve only hazard; the level of hazard is only one of several factors. For example, the complexity of the product is an important consideration. If 10 different food additives are included in a processed food, I wouldn't have great confidence in the willingness of consumers to go down a list that size to see if something hazardous is there. And if there were a separate warning for each additive, that would be ludicrous. Another factor is whether label information can be presented in a way that will be understood and heeded by the public. So hazard is not the only factor; we must balance many different ones. That's what makes my job so interesting.

Do you see any conflict between FDA's traditional role as a law enforcer or "cop," and its role in requiring labeling information from industry, which is more of an educational function?

A. Absolutely not. Some problems can be solved by making adequate information available and some can best be dealt with in other ways. There is no way you're going to get a quack product off the market simply

by labeling it. There are products that are intentionally fraudulent and the people who sell them are guilty of deliberately misleading the public. What you need to do in those cases is to get the product off the market and throw the people who are selling it in jail. So we need a strong enforcement posture. But enforcement is not enough, and I am committed to the concept that FDA must play an educational role as well as a "cop" role.

Dr. Kennedy, we've now had a decade of experience with the cigarette warning label, and cigarette smoking has not diminished. How effective is labeling in affecting consumer behavior?

I'm not sure I accept the assumption implicit in your question, that the cigarette warning has not worked. If you look at selected classes of people in American society-for example, middle and upper income males—you find a dramatic drop in the amount of cigarette usage. Women have increased their smoking to some extent, but that may be because they sense a broader series of choices available to them in all sorts of areas as a result of the women's movement. And women got a false sense of security from the early public health analyses indicating that they were less vulnerable to health problems from cigarette smoking than were men. But I am not prepared to accept the fact that the warning label did not have a powerful impact. We might be in a much worse situation were it not for the warning label and the warning advertising that was done for a period of time. Even more important may be the ban imposed by Congress against television advertising.

Turning to the broader question of whether we know well enough how labels work—this is a difficult question. I've been discussing it, as well as the issue of how you handle warnings in radio and television advertising, with Mike Pertschuk, the chairman of the Federal Trade Commission (FTC). We think a lot more serious social science research needs to be applied to this problem about how labels work. But



"... my common sense tells me that people want to know what they are buying and what risks they may be running, and that this information is most effective and useful when a purchasing decision is being made—that is, on the label of a product."

APRIL, 1978



"... we have nutrition labeling now only for certain foods—those that make a nutritional claim, or to which nutrients are added. We need to have it on all foods."

my common sense tells me that people want to know what they are buying and what risks they may be running, and that this information is most effective and useful when a purchasing decision is being made—that is, on the label of a product. So I'm not going to hold up our labeling initiatives until we study to death the question of labeling; we must move forward, while at the same time looking for better ways.

What other things are you discussing with the Federal Trade Commission?

A. I believe that food advertising should be allowed to make no claims that are not permitted on labels, and I've been discussing it with my colleagues at FTC who regulate food advertising. So far I've been quite pleased with the spirit of cooperation I've found at FTC on the subject of food labeling and advertising.

**Q.** Specifically, what initiatives need to be taken to improve food labeling?

Let me start by saving that I · consider food, and food labeling, to be at least as important to health as drug labeling. Good nutrition can prevent illness, while drugs only can cure or alleviate conditions that have not been prevented. As to specifics, we have nutrition labeling now only for certain foods-those that make a nutritional claim, or to which nutrients are added. We need to have it on all foods. I recognize this may require legislation, but it's terribly important. Another area we're looking at is standardized foods—that is, products that must be made according to a basic recipe written by the FDA. We can't require ingredient labeling on standardized foods, and even though FDA knows what's in the food that doesn't help consumers. For example, a person with allergies can't select from among different versions of a standardized food because there isn't an ingredient label. Again, new legislation may be needed.

Another matter  $\Gamma$ m interested in is naming of new foods. There has been some significant confusion on this issue. The question is how you name a new food that is similar to an existing

food. Do we just call it "imitation?" We've been trying to develop a policy that would allow the product to carry an entirely different name, and not be stigmatized with the "imitation" adjective, if the food has the same nutritional quality as the original product. Many consumers have told me that they are not satisfied with this, that it doesn't prevent them from being misled about the nature of the food. Besides, many foods that are labeled "imitation" have been quite successful, so the "imitation" adjective might not be as much of a stigma as we thought—mayonnaise is a good example. We may have to rethink the whole strategy of how we name foods that are similar to existing foods.

I'll be addressing the whole issue of food labeling in hearings this coming spring. We hope to get some information from the public to help us develop a long term Agency strategy in this

area.

What about color additives and labeling?

That's another area that needs more attention. There should be specific identification on food labels of the color additives used. As you know, under present law the label must declare only that a color additive has been added; the color additive does not have to be identified by name. But our knowledge of allergic reactions is increasing, and some people may want to avoid specific color additives, so labels should declare specific colors. And we intend to encourage industry to do so. At present, we are proposing to require that Yellow No. 5 be declared on all food labels by name because we have identified a specific allergic problem with it. About 100,000 people may be allergic to it, and they should be able to avoid it.

You've also spoken out on the need for new labeling on alcoholic beverages.

A. That's right. Alcoholic beverage labeling has been deemed by the courts to be within the province of the Bureau of Alcohol, Tobacco and Firearms (BATF) in the Treasury Department, so all we can do is work with them and recommend actions. I

am concerned about two aspects here. First, alcoholic beverages should carry ingredient statements, so consumers will know what they are buying and drinking. Second, and more importantly, I am concerned about the exposure of pregnant women to alcohol and the evidence that excessive drinking can adversely affect offspring. I have asked BATF to look into this. We already have warned doctors about this problem in the FDA DRUG BULLETIN, but I think the warning ought to be right there on the label so women can know of this risk.

Let's turn to drugs. A lot of people have expressed concern that labels on over-the-counter drugs are inadequate. How is FDA responding to this problem?

Our review of all over-the-counter (OTC) drugs is a major step toward improving the labels of these products, which I agree need improvement. We must make sure that the labels of OTC drugs are limited to claims that can be justified scientifically. Beyond that, I am concerned that OTC drug labels contain adequate warnings and cautions. After all, OTC drugs are by definition those that can

that OTC drug labels contain adequate warnings and cautions. After all, OTC drugs are by definition those that can be used by the consumer on the basis of label directions, and I'd like to see vast improvements in the way OTC drugs are labeled. Another point is that labels can be useful in changing the public's view of OTC drugs. Many consumers tend to think of OTC drugs casually, and do not accord these products the respect they are due. All drugs should be taken with utmost caution and the label has to convey some sense

of that caution. A larger concern of mine is not OTC drug labels, but advertising. It's no wonder the public doesn't treat OTC drugs with respect when they see the preposterous campaigns waged on behalf of some products. I am thinking specifically of a recent campaign between the aspirin and acetaminophen manufacturers, which really contributed little to better public understanding of these products. I've asked FTC to look into this campaign. I think OTC drug advertising over the years has tended too often to create diseases that don't exist and then offered solutions that ignore the fact that all drugs carry risks. I think these types of ads have been bad for our society.

Should FDA have authority over OTC drug advertising, as it does over prescription drug advertising?

A. Our cooperation with FTC has been good and so I don't see any reason to switch the authority over OTC drug advertising to FDA.

Probably the most controversial area of labeling involves patient package inserts for prescription drugs. Doctors have expressed fears that these inserts will interfere with their relationships with their patients. What is your view?

I am anxious to see more labeling for patients about prescription drugs. There are several reasons for this. First, an informed patient is apt to be more thoughtful and to follow instructions. There is a serious problem in this country of people not taking prescription medicine when they should, or not being told or not remembering what their doctors said about how often or when to take it. Package inserts for patients will provide that type of information. Second, people should be able to know what drugs they are taking—what benefits they can expect and what risks they run. Going to a doctor does not mean that we give up all responsibility for our own medical care.

My primary concern about patient package inserts is that there may be some tendency on the part of some patients to overreact to a long list of adverse reactions. They may become afraid to do what's best for them because they are frightened by the long list of side effects. We are being careful about that in writing the patient package inserts, and I don't think patients will be frightened—certainly not as frightened as some in the medical profession think they will be.

Patient labels are especially important when there are substantial risks with a drug of which patients have not been made aware. I am thinking in particular about estrogen drugs. These drugs are overused, but women must understand that prolonged use of estro-



"I think OTC drug advertising over the years has tended too often to create diseases that don't exist and then offered solutions that ignore the fact that all drugs carry risks."



"... I view the patient package insert as an important element of health education, as part of a process that makes people much more curious and much more involved in their own health care and thus more likely to do things that will lead to better health."

gen drugs can cause cancer. A large percentage of estrogen prescriptions are for purposes for which the drug has not been shown to be effective, and when we're talking about a risk of cancer, then the patient should be fully cognizant of that risk.

What about the charge that the inserts will interfere with the doctor-patient relationship?

A. I'm less concerned about that. Doctors ought to expect to be asked questions and should be willing to answer them. I think the inserts will lead to a better flow of information between doctor and patient.

What kinds of drugs, in your view, should have patient package inserts?

Several criteria come to mind right away. First, I would say drugs that need relatively detailed patient instructions with them are suitable candidates for patient package inserts; insulin is an example. Another criterion would be whether the drug is elective, as is the case with birth control pills and estrogen, for example. Obviously a person taking an elective drug must participate more fully in deciding whether to take it. Still another criterion is how long the drug is to be taken. A drug taken for long periods likely will pose a greater risk. Also, we would concentrate, at least at first, on drugs that have a significant share of the market.

If you had to put into a few sentences what you hope to accomplish with patient package inserts for prescription drugs, how would you put it?

A. The most important goal is to allow more informed decision-making about a particular therapy so a patient can participate with his or her doctor in making a decision. Knowledgeable people are apt to take better care of themselves. So I view the patient package insert as an important element of health education, as part of a process that makes people much more curious and much more involved in their own health care and thus more likely to do things that will lead to better health.

We've discussed advertising in several contexts. What is your view of advertising?

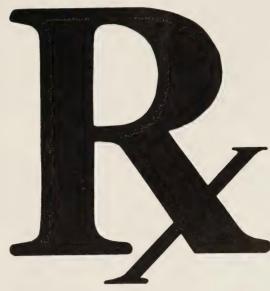
I begin with the premise that no one has the right to lie about a product, or to mislead people. In a complex world the Government must assure people that advertising is accurate. I think advertising is too little regulated now as it relates to health products. There are some very real questions in my mind as to whether some products should be advertised at all, or whether they should be advertised to certain groups of people, such as children. And often advertising does not provide the type of information needed for people to make informed judgments. That brings us back full cycle, in a sense, to labeling, because labels must provide full, accurate, balanced, objective information so people can decide in a rational way whether to buy a product. Advertising doesn't provide that kind of information.

O. Do you think there can be too much label information?

A. Yes, there can. We have to decide what really is important and what isn't, and concentrate on getting important information on product labels. We don't know enough right now about where the saturation point is and how people use information, so as we develop our labeling strategies we are going to have to evaluate each program.

Q. Looking down the road a bit, when you leave this office, what would you like to have accomplished in the area of labeling?

I would like to have revised our food statute to provide for more complete nutritional and ingredient listing. I would like to provide, either by statute or regulation, for increased information on both OTC and prescription drugs, with the emphasis on prescription drugs, because this is the area in which the most work needs to be done right now. I would also like to advance our knowledge about how people use information and how products should be labeled to allow people maximum capability to make informed choices in the marketplace.



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## A Day In The Pharmacy

#### An Experiment in Understanding

by
Alex Credle
District Sales Manager
Burroughs Wellcome

In recent years there has been a growing appreciation of the need for better cooperation between pharmacy and industry. The future unknowns have created needs in both areas that can best be met through better understanding of each other. In Maryland, a major step toward mutual understanding was taken by the Industry Relations Committee of the Maryland Pharmaceutical Association. Under the leadership of Mel Rubin, then President of the MPhA, and George Stevenson, Chairman of the Industry Relations Committee, a program was developed to have new pharmaceutical representatives spend one or two days in a pharmacy. The purpose was to gain insight into the operation of a pharmacy. It was felt that this would be mutually beneficial in that the pharmacist's needs would be understood by the representative, and the representative would then be better prepared to meet these needs.

The specifics of the program were designed by Jerry Block, RPh, a practicing pharmacist and an instructor in the Extern program of the University of Maryland School of Pharmacy, with additional input from William Brown, Manager of Pharmacy Relations of Geigy, and myself. The program outline is as follows:

Plans for "Day with Medical Representative Trainee."

- I. Greetings
- II. Tour of Pharmacy
- III. Stock arrangement (ABC according to manufacturer)
- IV. Introduction into the prescription area
- Family Record System (note time and work involved in setting up and maintaining)
- VI. Possible areas of discussion
  - A. What is an excellent medical representative? (pnarmacy point of view)
  - B. What can a medical representative offer a pharmacy?
  - C. What can a pharmacy offer a medical representative?
  - Questions by the trainee (previous thought should be given to this)
  - E. What is involved in filling a prescription?
    - Receiving the prescription and interviewing the patient
    - 2. Checking Family Record
    - 3. Filling prescription
      - a. Third Party Plans
      - b. Checking errors with physician
    - 4. Entering data into family record (note time involved)
    - 5 Presenting prescription to patient
    - 6. Patient consultation



Maureen McCuun, a new Burroughs Wellcome representative recently spent a day with Jerry Block, owner of the Curtis Bay Pharmacy in Baltimore.



F. Third Party Plans

1. Note time consumed and special problems

Note volume and variety of un-standardized regulations

 Receiving prescription by phone from physician, nurse etc.

H. Pricing

1. Prescriptions

a. What is a Fee System?

b. What are modifications of fee systems?

c. What is percent mark-up?

d. Variations of above

2. OTC's

a. How is consumer dollar broken down (homework)

Gross and net profit, cost of merchandise, expenses, taxes, etc.

 How manufacturers pricing policies affect community pharmacy

. Differential Pricing

5. Incremental Pricing

6. Discounting & Buying

Turnover — the need to be fluid

 Wise Buying vs. Overloading — how manufacturer can help pharmacist

Returned Goods Policies of various manufacturers

1. Good Policies

2. Bad Policies

Money Flow for Month of Business

In addition to this program, Mr. Block assigned each representative some assignments involving pricing, gross profits, and monthly operating costs. This assured a basic understanding of pharmacy terminology as a starting place for the day(s).

Two Burroughs Wellcome Pharmaceutical Representatives have initiated the program. The feedback from both has been very positive. Sample comments were:

"The multitude of situations which arise throughout the day must be experienced first hand to be believed. It is a many faceted role which the pharmacist fulfills in order to best meet the needs of his patient. It is here that the pharmaceutical company plays its all-important role, by meeting the needs of the pharmacist..."

"The example you have set, Mr. Block, shall prove to be of great value to me in my everyday encounters. The extra time you take during the day to serve your patients exemplifies the type of professionalism I hope to achieve in my efforts. Again thank you for a most valuable learning experience."



Photo courtesy Paramount Studio



"The workings of a pharmacy are very intricate and I thank you for taking the time to show me your views concerning your place in the health care system."

"The time involved in filling a prescription was overwhelming from my point of reference, and I quickly realized that counting capsules or tablets did not constitute the filling of a prescription. The importance of a family record system became very apparent as well as the prevalence of third-party plans and their accompanying paperwork."

"... I realize now that turnover rate is very important when taking a deal... There is no doubt in my mind that my time in your pharmacy was well spent, and I would encourage all new pharmaceutical representatives to participate in such a program."

Jerry Block's comments were similar in their analysis of the program:

"Our day was fruitful and interesting, however, too often lack of time forced us to cover areas superficially that would have been better covered in depth... My feeling is that this program is worthwhile, and has great potential. This experience has fortified that feeling on my part."

The mutual benefits are obvious as these representatives are now better prepared to recognize, understand, and try to meet the needs of pharmacists. The time spent was an investment in improved understanding between industry and the Maryland Pharmaceutical Association. The success of this program indicates that it could be matched by pharmacy and industry associations across the country.

## Pharmacist Liability Under the New Drug Product Selection Law

by ROBERT R. MICHAEL Legislative Committee Member Maryland Trial Lawyers' Assoc.

Presented to BMPA meeting on February 23, 1978

#### Pharmacists' Liability

#### I. Pharmacists' Liability - In General

Simply stated, a pharmacist in filling a prescription is under a duty to use that degree of care and skill which is expected of a reasonably competent practitioner in the same class to which he belongs, acting in the same or similar circumstances. This is the legal definition by which a pharmacist's conduct would be judged in assessing whether he had incurred liability as a result of his professional activities.

#### II. Statutory Provision — Old and New

A. Former Article 43 Section 273A — "Dispensing different drug product from that specified in prescription."

Former Article 43 Section 273A of the Maryland Annotated Code was effective as of December 1, 1972, and basically permitted a pharmacist the right to substitute a "different brand name or nonbrand name . . ." drug in lieu of the brand name drug contained in the doctor's prescription. Where substitutions were made, however, the pharmacist was required in each case to "... immediately transmit the notice in writing to the prescriber specifying the drug product actually dispensed and the name of the manufacturer or distributor." The pharmacist's right to substitute was unbridled unless the physican "... explicitly states otherwise . . . " in the case of an oral prescription or unless the physician ''... indicates in his own writing or by initialing an appropriate imprinted statement . . . " to the contrary in the case of a written prescription. It is interesting to note that no criminal or other administrative sanctions were imposed by the legislature for the pharmacist's failure to render the required report.

B. Present Article 43 Section 273A — "Dispensing different drug product from that specified in prescription."

The present Article 43 Section 273A of the Maryland Annotated Code became effective as of July 1, 1977, and basically permits the pharmacist the right to substitute a "... drug product of the same dosage form and

strength . . ." provided the substituted drug product is ... generically equivalent." Under the present law, the pharmacist must in the case of a substitution perform two (2) tasks: (1) First, he must " ... record on the prescription and maintain as a record the name and manufacturer of the drug product dispensed. (2) Secondly, the pharmacist must notify the patient in writing if the dispensed drug is the "... generic equivalent of the prescribed drug." (Emphasis added). The pharmacist's right to substitute is, again, unbridled unless the physician " . . . expressly indicates that the prescription is to be dispensed as directed.' A new wrinkle has been added under the present section, however, and that is that under the current law the Department of Health and Mental Hygiene of the State of Maryland is charged with the duty and responsibility for assembling and updating on a regular six (6) month basis a list called a "formulary." This list is supposed to contain ' ... drugs for which drug product selection is restricted or prohibited . . . " on the basis of " . . . actual or potential bio-inequivalency of therapeutic significance.'

It is likewise interesting to note that again the Legislature has imposed no criminal or administrative sanctions for violations as to any of the new provisions.

Significant Differences Between the Old and New Statutory Provisions

Thus, there are four (4) significant distinctions between the old and the new statutory provisions:

 Under the new section, the pharmacist is no longer required to notify the physician in writing as to the identity of the substituted drug and its manufacturer or distributor.

2. A pharmacist may unilaterally substitute a generic drug for a brand name drug provided that such substitution is not (a) expressly prohibited by the physician to the effect that the prescription must be filled exactly as written, and provided further that (b) the substituted drug does not appear on the formulary list as an actual or potential bioinequivalent of the brand name drug.

3. A pharmacist must now maintain a written record of each generic drug substitution on the prescription which shall include the name of the substituted drug as well as its

manufacturer.

 A pharmacist must now notify the patient in writing of the substitution of a generic for a brand name drug.

### III. Impact of the New Statutory Provision on Pharmacists A. Negligence

Simply stated, there is no change or alteration in the professional responsibility imposed on the pharmacist by the new section. The same standard of care in filling the prescription under the old statutory section remains under the new statutory section. This standard is unaffected by any of the significant differences between the old and the new sections as noted above, which concern themselves primarily with recording and administrative functions.

However, it is clear that a pharmacist in the State of Maryland must be familiar with and be knowledgeable as to those drugs that are contraindicated by virtue of their inclusion on the formulary list as a bio-inequivalent. Therefore, it is conceivable that the dispensing of a generic drug on the formulary list in substitution for a brand name drug, and which results in injury or detriment to the patient, could form the basis of a negligence action against the pharmacist. By means of example, however, this is no different than continuing to dispense any drug for which there is actual knowledge of harmful effect. Hence, the formulary list will function more as a shield of the pharmacist than as the sword of the litigator.

#### B. Products Liability

If one assumes, as has the State Legislature, that generically equivalent drugs are as safe and effective as brand name drugs, then this new section should likewise have no impact on the pharmacist in the area of products liability. The only logical manner in which a pharmacist could be adversely affected is if the generically equivalent drugs are, in fact, defective. If this should occur, then there would be a general increase in suits against pharmacists as well as prescribing physicians and drug manufacturers. If, however, the generic drugs do not demonstrate any greater incidence of defect than brand name drugs, then one would

assume that there would be no danger of an increase in suits against pharmacists, physicians, and drug manufacturers on a products liability basis.

#### IV. Conclusion

As noted above, the new statutory provision retains the pharmacist's right to make substitutions. It does not affect his already established responsibility for such substitutions. Please remember that the above is a legal opinion and not a court decision since none is yet available on this specific issue. However, it does represent our best judgment at this time and is respectfully submitted for your guidance.





April 6 (Thurs.) — MPhA Board of Trustees Meeting

April 13 (Thurs.) — MPhA-MSHP Joint Meeting, Kelly Building

April 16 (Sun.) — AZO Berman Seminar

April 20 (Thurs.) — MPhA Spring Regional, Ouality Inn, Towson

May 13-18 — MPhA Montreal Trip — APhA Meeting

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## Successful Swain Seminar Studies Geriatric Medicine



The Robert Lee Swain Pharmacy Seminar was held on March 5, 1978 at the Center of Adult Education at College Park, Maryland.



The subject of the Seminar was Geropharmacy and Geriatric Medicine. Between sessions, pharmacists were able to consult with individual faculty members on pharmaceutical care services to nursing homes and nursing home patients.

Photo courtesy Paramount Studio



One of many outstanding speakers, Thomas C. Majerus, Pharm.D., presented "Antibiotics in the Treatment of the Elderly."



Pictured at the luncheon are (left to right) Phillip H. Cogan, Seminar Chairman; Henry G Seidman, Director of Continuing Education for the School of Pharmacy and Chairman of the Association's C.E. Committee; Dean William J. Kinnard, Jr., Dean of the School of Pharmacy; and Mrs. William Kinnard, Jr. Dean Kinnard delivered remarks at the luncheon.



The Baltimore Metropolitan Pharmaceutical Association's meeting of February 23rd featured an explanation of the Medicaid Survey which is being conducted by the State. Pictured are (left to right) Jake Miller, special pharmacist consultant to the accounting firm of Myers and Stauffer and President-elect of the A.Ph.A.; Milton Sappe, President of the BMPA; and Bruce Myers from the Kansas accounting firm.



Ronald Lubman, Convention and Trips Chairman, makes an announcement about upcoming Association travel bargains.

## BMPA Meeting Draws Over 100 Pharmacists



A large turnout at the Ramada Inn on the Beltway contributed to the success of the program.

Many pharmacists came to hear the program on the Maryland Drug Product Selection Law. Those who presented the topic were (left to right): Robert R. Michael, J.D., member of the Trial Lawyers Association's Committee on Legislation; Ralph Shangraw, Ph.D., from the University of Maryland School of Pharmacy; and Paul Freiman, Commissioner of the Maryland Board of Pharmacy.

## When is a side effect a sign of effectiveness

With Brethine, it is when the highly effective action of the drug affects skeletal muscle as well as bronchial smooth muscle, causing tremor in some patients.

It is important for you, the pharmacist, to realize that Brethine is a  $\beta_2$ adrenergic agonist. The result of this action will be highly effective bronchodilation ( $\beta_2$  receptors in bronchial smooth muscle) and, sometimes, tremor ( $\beta_2$  receptors in skeletal muscle of particularly sensitive patients).

If you are asked about tremor, you should be aware that tremor usually temporary, that it is a sign that Brethine is working and that easier breathing will continue eve after the tremor subsides (usually in a week or two).

Patients should follow a bedtime, morning, and midafternoon dosage schedule to avoid overlapping dosage. They should minimize their intake of coffee and other caffeinated beverages and see their physician.



Brethine¹ brand of terbutaline sulfate
Tablets 5 mg. Tablets 2.5 mg. Before prescribing or
administering, please consult complete product
information, a summary of which follows:
Tablets contain 5 mg. (equivalent to 4.1 mg. of free
base) or 2.5 mg. (equivalent to 2.05 mg. of free base) of
Brethine, brand of terbutaline sulfate.
Indications: As a bronchodilator for bronchial
asthma and for reversible bronchospasm which may
occur in association with bronchits and emphysema.
Contraindications: Known hypersensitivity to
sympathemimetic amines.
Warnings: Usage in Pregnancy: The safety of the
use of Brethine, brand of terbutaline sulfate, in human

pregnancy has not been established. The use of the drug in pregnancy, lactation, or women of childbearing potential requires that the expected therapeutic benefit of the drug be weighed against its possible hazards to the mother or child.

Usage in Pediatrics: Brethine, brand of terbutatine sulfate, tablets are not presently recommended for children below the age of twelve years due to insufficient clinical data in this pediatric group.

Precautions: Brethine, brand of terbutatine sulfate, should be used with caution in patients with diabetes, hypertension, and hyperthyroidism. As with other sympathomimatic bronchodilator agents.

Brethine, brand of terbutaline sulfate, should be

administered cautiously to cardiac patients, especiall those with associated arrhythmias. Although the concomilant use of Brethine, brand of terbutaline suitate with other sympathemimetic agents is not recommended, the use of an aerosol bronchodilator of the adrenergic stimulant type for the relief of an acute bronchospasm is not precluded in patients receiving chronic oral Brethine, brand of terbutaline suifate.

therapy.

Adverse Reactions: Commonly observed side

Adverse Reactions and tremor. Other reaffects include nervousness and tremor. Other re-ported reactions include headache, increased heart rate, palpitations, drowsiness, nausea, vomiting, and sweating. These reactions are generally transient in



## The Evolution of the Medicine Cabinet

by John C. Krantz, Jr., Ph.D. Professor Emeritus Department of Pharmacology University of Maryland School of Medicine

#### The Evolution of the Medicine Cabinet

When America was largely a farm community with a few scattered cities, most families grew their own herbal medicines. In addition, the fields were abundant with plants that were alleged to possess medicinal activity. When a person suffered from stomach discomfort there was rhubarb growing in the garden adjacent to the house. Similarly, if the ailment was a grip-like condition there was the bark of the wild cherry tree which served to ameliorate the symptoms. Most of the drugs used in the early days of our nation were of vegetable origin.

As the population increased, more land for agricultural purposes was needed to supply food to the nation. Therefore it became necessary to cultivate those plants that were used for medicinal purposes and private cultivation of medicinal plants diminished. The drugs from both the vegetable and mineral kingdoms had to be purchased and generally stored in the home to meet the emergency of a sudden illness. In the early days of our nation, drugs were usually stored on a shelf over the kitchen sink owing to the availability of drinking water. With the installation of the bathroom with its tub and water supply, the storage of drugs was transferred to the shelf above the bathroom washbasin. As the number of drugs in bottles, boxes and tubes increased, the birth of the medicine cabinet occurred and it has enjoyed an interesting evolution in its contents through the everlengthening past. Let us take a look at the contents of a typical medicine cabinet at the dawn of the century.

#### 1. Relief of Pain

Acetanilid — used for headache
Mustard Plaster — used for muscular pain
Belladona Plaster — used for muscular pain
Sloan's Liniment — used for muscular pain
Oil of Wintergreen — used for muscular pain
Soap Liniment — used for muscular pain
Chloroform Liniment — used for muscular pain

#### 2. Laxatives and Purgatives

Epsom Salt — used as a purgative Rochelle Salt — used as a purgative Castor Oil — used as a purgative Cathartic Pills — used as a purgative Calomel — used as a purgative Castoria — used as a laxative Syrup of Senna — used as a laxative Family Physician — used as a laxative

#### 3. Antidiarrhea Drugs

Paregoric

#### ...........

Antacids
 Bicarbonate of Soda
 Milk of Magnesia

#### 5. Antiseptics

Alcohol Tincture of Iodine Bichloride of Mercury Listerine

#### 6. Dysmenorrhea

Pinkham's Vegetable Compound Wine of Cardui Hayden's Viburnum Compound

#### 7. Grip-like Conditions — Cold, Cough

Acetanilid Quinine Wild Cherry Bark Syrup Brown Mixture Syrup of Ipecac

#### 8. Stimulants

Smelling Salts Aromatic Spirit of Ammonia Coffee

#### 9. Sedatives

Paregoric Laudanum Tincture of Valerium

#### 10 Skin Irritation

Carbolated Vaseline

#### 11 Accessories

Raw Cotton Cloth Bandages

In reading the foregoing lists of drugs one recognizes several that have endured through the present scientific age of medicine.

Let us now judge the foregoing categories with the drugs one is likely to find, by virtue of the evolutionary process, three-quarters of a century later.

#### 1 Relief of Pain

Aspirin — Headache Aspirin — Dosage forms Alka-Seltzer Bufferin and others Acetaminophen, Tylenol

#### 2. Muscular Pain

Aspirin and its dosage forms
Oil of Wintergreen
Analgesic Balms

#### 3. Purgatives

Epsom Salt
Phenolphthalein formulations such as ExLax

#### 4. Laxatives

Milk of Magnesia Senna preparations — Senokot Metamucil

#### 5. Anti-diarrhea Drugs

Kaopectate Paregoric

#### 6. Antiseptics

Alcohol Merthiolate Zephiran chloride Listerine Band aids

#### 7. Antacids

Alka Seltzer Rolaids Milk of Magnesia DiGel

#### 8. Dysmenorrhea

Antifertility products
Aspirin or its dosage formulation for pain

#### 9. Grip-like Conditions - Cold, Cough

Aspirin or its dosage formulation for muscular pain or fever
Neosynephrine — Dristan for nasal congestion
Destromethorphan (Romilar) for cough

#### 10 Stimulants

Caffeine Smelling Salts

#### 11. Sedatives

Nytol Sominex

#### 12. Skin Irritation

Carbolated Vaseline Vanishing Cream

#### 13. Accessories

Clinical Thermometer Sterile Bandage Absorbent Cotton Ace Bandage

One must realize that the medicine cabinet today contains, as a rule, usually only those products that may be purchased without a prescription of a physician or dentist. These present OTC drugs have many advantages over the drugs in the selection of three-quarters of a century ago. Many have endured the acid test of time. Many new chemical agents that were once prescription drugs are now available by the OTC process. They are carefully controlled by their manufacturer and must comply to rigid standards. In the products of former years there was no disclosure of formulas on the label. The present day OTC remedies are required by law to give a complete disclosure of their ingredients and amounts on the label. Our OTC selection is simple but effective. The record justifies this statement since more than one half of the medicine used in this country is of the OTC variety. For example, we consume approximately 20 tons of aspirin daily. Most of the ingredients of our present day OTC medicines contain drugs recognized by the United States Pharmacopeia and must comply to its standards of identity and purity. Indeed, we can be proud and grateful that the evolution of drugs in the medicine cabinet has kept abreast of the progress in other areas of human endeavor.

If you think Purepacis a quality generic,
YOU'TE Right!

If you think Purepac is expensive,

You're Wrong!

Purepac's line of over 300 generics is one of the lowest priced brands available to pharmacists.

Sometimes, when comparing specific prices, you may find a Purepac generic costs you a fraction of a cent more per tablet or capsule than generics available from other sources.

Why does this fraction of a cent difference occur? Because Purepac spends more to protect your professional integrity. Purepac manufactures most of its major generics, provides product liability protection, has its own quality control laboratories and tests its products to insure you consistency in size. shape, color and product uniformity.

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#### HECK THE BIG PLUS FEATURES:

Complete Product Information.
Complete OTC and RX Pricing Stickers.
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Deal Contents Have Price Stickers.
Price Stickers for Selected Full Cases.
NDC Numbers on All RX Products.
Customized Pricing.
Two Price System.

Store Identification Labels.

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LOEWY DRUG CO. 6801 QUAD AVENUE, BALTIMORE, MD. 21237 YES, I'd like to get more FACTS ABOUT SPACE:

NAME \_\_\_\_\_

TITLE

STORE .

ADDRESS \_

CITY

\_ STATE \_\_\_

ZIP

## **Drug Product Problem Report**

#### Examples of actions resulting from pharmanists' reports

The case studies presented below are intended to serve as examples of the kinds of action that may be taken through the Drug Product Problem Reporting Program. While these results are from actual reports received, they are included for general illustrative purposes only. It is hoped that these examples will indicate to the pharmacist reader some of the areas where he or she may want to be alert. No reflection on any specific manufacturer, distributor, pharmacist, or product is intended or should be inferred from the case studies.

## Bronchodilator Closures Changed After Pharmacists' Reports

Numerous reports about the presence of particulate matter in a bronchodilator solution used in inhalation therapy were received through the Drug Product Problem Reporting Program from pharmacists across the nation during 1976 and 1977. Three FDA inspections at the manufacturer's plant ultimately revealed that the particulate matter came from a new cap/liner system which the company was not controlling adequately. As a result of the reports and FDA's findings, the company discontinued the new cap/liner system and converted to a bakelite closure system. Meanwhile, it intends to conduct identity testing of the liner material used in the other system.

#### Market Withdrawal

"Rectal applicator does not fit on tube of ointment" was the complaint of a community pharmacist from Illinois. The lot number involved was voluntarily recalled by the manufacturer from all accounts to which this hemorrhoidal product had been distributed.

#### **Gross Nuclear Contamination of Cartons**

A nuclear pharmacist in California reported continuing problems with gross contamination on the interior of the shipping cartons for an I-131 oral solution and 99Mo-99mTc generator. Since the contamination involved a long-lived radiopharmaceutical, it created trash disposal problems. The pharmacist also reported that although he had been assured by the manufacturer that the problem would be "alleviated," no noticeable improvements had occurred. An FDA inspection at the company's plant indicated that the contamination came from the filling and sealing equipment. The firm is now monitoring the production equipment during manufac-

ture of these iodine sources, and a health physics representative is making daily checks of the production area to identify potential trouble spots. Concerning the 99Mo-99mTc generator, the manufacturer is placing them on sheets of disposable paper to insulate them from possible contamination; in addition, it has instructed assembly line personnel on proper handling techniques to insure that generators are not contaminated, and it has added to the line an operator whose job it is to wipe off every generator.

#### Label Misprint Leads to Recall

A Kentucky hospital pharmacist's report pointed out a discrepancy in labeling; "Drug is labeled as rauwolfia serpentina 100 gm. The patient identification portion of the package states 100 mg." The repacker/distributor recalled this product in unit-dose packaging.

### Three Recalls on Chloral Hydrate Follow Pharmacists' Reports

A large number of reports from pharmacists concerning leaking capsules of chloral hydrate prompted FDA to issue an assignment to its district offices asking them to examine the manufacturer's stability data for this product. Three separate recalls have thus far resulted; (1) one repackaging company agreed to a recall on two lots of chloral hydrate capsules when it was informed of the leakage problem — the FDA follow-up investigation showed that the repackager had used a five-year expiration date without acceptable stability date, while the manufacturer recommends an 18-month expiration date; (2) another repackager recalled one lot, made by the same manufacturer as in the previous case, when examination showed that 4.5% of the capsules had leaked; (3) a third repackager recalled one lot - made by a different manufacturer - at the primary level because the capsules were leaking at the seams.

#### Contraindicated Products' Names Were Too Similar

A state pharmaceutical association executive reported the concern of several of his members over the marketing of two drug products under similar brand names. He wrote that the members had found "the similarity of these brand names particularly disturbing since (one proudct) is a diuretic quite frequently used in hypertension, while the second (a decongestant) is specifically contraindicated in that disease state." The manufacturer of the second, more-recently marketed decongestant product agreed to alter its name.

#### Report Prompted a Color Change for Safety

"Could be very hazardous" was the comment from a pharmacy supervisor at a hospital in New York State, regarding the similarities between single-dose vials of one company's atropine sulfate and sodium heparin injections. She commented further that the vials were "not only identical in size and color of cap, but the printed wording on the vials is almost the same color." The manufacturer agreed, and changed the color of the sodium heparin vial's flip-off cap to distinguish it from that of the atropine sulfate.

#### Company Modifies Its Formulation

Responding to a Texas hospital pharmacist's report of "sticking" and "excessive powder," the manufacturer of pseudoephedrine hydrochloride 60-mg tablets examined a file sample, found them to be "slightly more brittle than desirable," and had its development laboratory modify the formulation to obtain a "slightly less brittle and harder" tablet. In notifying the pharmacist of these actions, the firm stated, "Professional observation and reporting is an invaluable adjunct to our control system and its importance as a check on our control efforts cannot be over-emphasized."

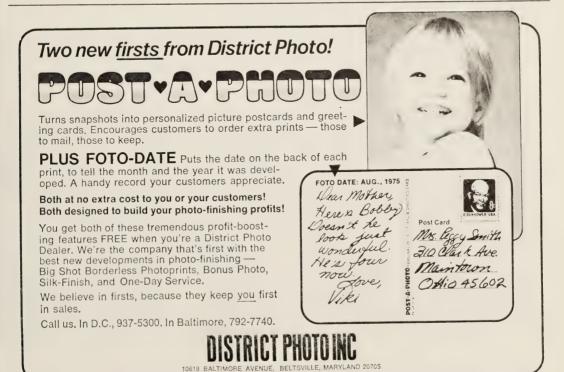
#### Capsule Variations Lead to Phenytoin Recall

Two separate reports from pharmacists in Illinois contributed to the recall of several lots of phenytoin

sodium capsules by the manufacturer. Both pharmacists noted variations in size and weight of the capsules, and one had even performed a weight variation test on the capsules — he found that 20 filled capsules, chosen at random, varied from 164.6 mg to 229.2 mg, while the empty capsule shells varied only from 47.3 mg to 49.7 mg. (For a description of a simple in-pharmacy test for weight variations of capsules, see p. 670 of USP XIX). As a follow-up to these reports, an FDA investigation at the manufacturer's plant revealed that several lots of the product were manufactured under inadequate Good Manufacturing Practices and that they failed to comply with USP content uniformity requirements. The company recalled all of the lots involved.

#### Unit-Dose Blister Seals Were Breaking

Commenting that "upon separating unit dose packages, the product seal breaks and the capsule is exposed," a Virginia pharmacist reported difficulties with one lot of unit-dose strips containing chlordiazepoxide capsules. To correct the problem, the manufacturer indicated that the procedure for applying the heat seal closure material was being modified to provide a more even coating between the backing material and the blister, and that it had modified the knives used to make the perforations between the blisters, thus permitting easier separation. The firm also indicated that it was investigating alternative packaging materials in the hope that a stronger bond could be produced between the blister and the backing.





Representative Barbara A. Mikulski from the Third Congressional District in Baltimore is greeted by Alumni Association Past President Henry G. Seidman. Representative Milkulski delivered the featured address at the Association's Dinner Meeting on March 12, 1978.

Several members of the University of Maryland School of Pharmacy class of 1938 attended the meeting.

## Highlights of the Pharmacy Alumni Association's March Dinner Meeting

Photo courtesy of Paramount Photo Service



The Pharmacy Class of '43 was well represented at the meeting which was held at Martin's West in Baltimore.



Benjamin F. Allen, Ph.D. (left) was presented with the Association's Honorary President's plaque from Henry G. Seidman.

### LETTERS





# Rite Aid

Dear Sir

Due to our expansion program in Maryland we will have full time positions available for registered pharmacists throughout the state.

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Martha D. Schneider has been assigned to the Baltimore, Maryland, territory as a Professional Sales Representative for Smith Kline & French Laboratories, the pharmaceutical division of Smith Kline Corporation.

Before joining SK&F, Ms. Schneider was a sales representative for Parke Davis & Company in Hunt Valley. She received a Bachelor's Degree from West Chester State College, Pennsylvania in 1972.

Ms. Schneider lives in Owings Mills.



700 East Joppa Road Baltimore, Maryland 21204

The Maryland Pharmaceutical Association has recently endorsed a group major medical health insurance plan from Blue Cross/Blue Shield of Maryland. We are currently in an open enrollment period for members family and non-pharmacist employees of members. Contact the M.Ph.A. office or Blue Cross/Blue Shield for the details.



THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association MAY, 1978 VOL. 54

NO. 5



## **Putting a Computer in Your Pharmacy??**

(see page 6) - George Pennebaker, Pharm.D.

## Report from the Board of Pharmacy

- Paul Freiman, Commissioner

The list of Maryland District Sales Representatives

#### THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET BALTIMORE MARYLAND 21201 TELEPHONE 301/727-0746



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Change of address may be made by sending old address (as it appears on your journal) and new address with zip code number. Allow four weeks for changeover. APhA members — please include APhA number.

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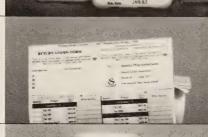
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### What have you done to us lately?

In an apparent effort to throw crumbs to the pharmacists in Maryland, the Blue Cross plan increased its fee to \$2.25 as the Medicaid program goes to \$2.45. This is really the proverbial straw to break the camel's back. The most talked about problem in the profession is the failure to be recognized as professionals and to be paid for services. The pharmacists in the District of Columbia got an increase from \$1.80 to \$2.59 through a refusal to submit to the confiscatory policies of the Department of Human Resources.

After the successful action taken by the pharmacists, a group of physicians took job action against the Group Health Association, which resulted in a salary of \$66,000 with a seven hour clinic workday and provision for Malpractice Insurance.

While I agree that physicians are entitled to adequate fee-for-service, why are we always expected to provide service-for-free. While at the same time offering low-low prices, senior citizens discounts, patient profiles, etc.

Individuals who do not feel we are properly treated should ask these third-party administrators to take a scrutinizing look at the service we are asked to provide. We cannot keep our feelings to ourselves and expect a re-evaluation of the fee determination process.

For information on how you can express your concerns properly, contact Dave Banta at the Association office and support Pharmpac for legislative relief.

Silar Doal

## Calculated To Make A Molehill Out Of A Mountain

If you think you're ready for bauds, bytes and boots, computerization, once you get the hang of it, will forever change your style of practice. As for the size of the investment, you'll outget more than you input.

#### by George Pennebaker

Computers are no longer the futuristic dream. They are here to-day, doing their work in many otherwise typical community pharmacies. But while they relieve burdens — especially paperwork — they also create questions, such as: Is a computer the right thing for my pharmacy? If it is, which one?

It is not difficult to take some of the mystery out of the words and equipment and provide a number of points to think about as you encounter the various systems. It is all keyed to a check-off sheet (see page 00) which will help you evaluate your pharmacy's needs and the features of the various systems.

As with any new thing, there are many opinions about what is right. But it is best that you consider all the facts and develop your own conclusions.

Basically, computers are just highly-organized sets of ON and OFF switches — millions of them, changing rapidly, but always in a predetermined manner. They are fast.

And they are dumb. They only do what they have been told, or "programmed" to do, but they do it so fast they sometimes appear to be smart. They can file and find information and they can do calculations. Whether or not you will find a computer useful is a matter of whether or not

it files and finds the information you need and whether or not it does the calculations you need. You do not need the astronauts' computer to run your pharmacy any more than you need a trigonometry calculator to balance your checkbook.

Computer salesmen often use words that seem to mean one thing and turn out to mean another. "Our computer can . . . " usually means that the computer is capable of doing a certain task but has not yet been taught how to. A "drug interaction notification system capability" can mean that the computer checks each new prescription against the patient's profile and immediately notifies you of a probable interaction and its nature and the details of the interacting prescription. Or, it can mean that the computer tells you at the end of the month that a patient received a drug that is known to interact with other drugs, implying that maybe you check it. Or, it may be some place in between.

"Our computer will" do this or that often means that in the future it will do that task. Care should be exercised in reading advertisements and listening to computer people.

The simulating of a desired function is an oft-used sales technique. This is like driving a car in what is now the "Fifty-Cent Arcade." You put a coin in the slot, work the gas pedal and brakes, and steer through the maze on the screen before you. A lot of it looks and feels real but it isn't.

In simulation situations the computer operator or salesperson is very careful about letting anybody else touch anything, especially when it involves filing information or asking the system to retrieve or digest something a little bit unusual. Simulation is commonly used during the development phases. Do not sign up on the basis of a simulation unless you are willing to help de-bug the system. If you have any doubts about what you are seeing, ask if it is a simulation. Better yet, ask if you can push the buttons.

There are a number of functions to look for in a pharmacy computer. Each needs to be evaluated with regard to your pharmacy in terms of how important it is to you to have that function, now and in the future. Then, examine the various systems with regard to their ability to perform the functions.

Patient Profiles: Does the profile hold all of the information you want to know about the patient and his prescriptions? Is the format readable? How long does it take to get a profile? How many prescriptions will a profile hold?

Interaction Notification: What exactly does the system tell you and when? What are the criteria used by the system to detect an interaction? When an interaction is identified, what happens next?

Allergy Notification: Same as Interactions.

George Pennebaker, Pharm.D., is president of ApotheTech, Inc., a California computer firm. He is a member of the Sacramento Valley local association.

Warning Notices: Some systems tell you which auxiliary labels to put on the container, others print out canned warning notices automatically. Again, determining what fits your practice is important.

Label Printing: Assume that the label is legally complete, but it is worth checking. In addition, its legibility and size (does it fit on a 7-dram vial?) are important.

Pricing: Prices consist of ingredient costs plus your fee or markup. You should be interested in who is entering the ingredient costs and what definition of cost is used. Right now, the computer is right in the middle of the AWP-AAC controversy because some systems can handle either one easily, while others may have problems.

The pricing system for your private prescriptions should be flexible enough to accommodate your needs, now and in the future. Changing it should also be a relatively straightforward operation. Pricing for Medicaid should be flexible enough to deal with the sudden changes that can occur in the program. The same is true of other third parties.

Medicaid Billing: The main question here is how much information will you have to look up for each Medicaid transaction. It can range from not looking up anything to having to check to see if the drug is covered, its code, the patient's number, etc. You should also be interested in the method used to reconcile Medicaid payments against billings.

Does the computer know what to do when the claim involves a rejection? Medicaid is an excellent example of the problems some computers may encounter in crossing state borders. A computer working in some other state is not likely to have the Texas formats entered on its files. Obviously, Texas computers pose the same problem for other states. This is often the point at which the computer person will use the words can, will, and is capable of.

Other Third Parties. There are a variety of ways to handle claims for third parties. Some systems have the capability to send information directly from their computer to the

third party's computer. This is usually called tape-to-tape transfer. Other systems fill out the forms for you — some right away, others at the end of the day, week or month. Another system may provide you with all the information to fill out the form, but will not actually print it. Some do nothing about third parties.

When evaluating this feature, it is advisable to determine exactly how much time you are now spending on third-party forms and how much time each system will save. By the way, the tape-to-tape transfer systems may still require a hand-entry log be kept in the pharmacy, in which each transaction is recorded and signed for by the patient so that the third party will have an audit trail.

Controlled Drug Accountability: The Drug Enforcement Administration has specified detailed requirements that must be met by these systems. Do not assume that the system you are looking at meets these requirements.

Accounts Receivable: There are a variety of accounts-receivable programs available. In fact, some of the "pharmacy" systems now being marketed started out as general business accounts-receivable systems and have been expanded in varying degrees to accomplish pharmacy functions. Does the system fit in with your operation? Does it accomplish the functions you need or provide too little, or too much?

Management Reports: It seems that each computer company has its own idea of what a pharmacist needs in the way of reports. One of the modern management problems is the proliferation of reports that nobody reads. It is easy to overrate — or for that matter to underrate — the value of reports that a system may produce. Again, is it important to your practice?

In addition to evaluating the various functions of a system, you should take into account other considerations, such as **Output Mechanism**. Essentially, computers tell you things in one of two ways: by printing it out on paper or by displaying it on a CRT (TV screen). Either way can have its problems. Printing is slow

#### THE LAYMAN'S GLOSSARY

Hardware — The pieces of equipment: printers, keyboards, the computer itself, memory devices, etc.

**Software or Programs** — The instructions that tell the hardware what to do.

**Programming**—Putting together the software.

**Data entry** — Entry of specific information: patients, prescribers, drugs, etc.

Simply stated, the software tells the hardware what to do with the data that is entered.

and uses up a lot of paper. CRT display is fast but temporary. Some systems have the ability to selectively print information that is displayed on the CRT. Other considerations:

Hardware. Is the hardware appropriate for the job that needs to be done? Million-word-a-minute printers are silly in a pharmacy. Conversely, hardware that is slow and awkward is probably just as questionable. What is its size? Is it noisy? How much modification of the pharmacy will be needed?

Space: There are some systems that only occupy as much space as a large typewriter, just as there are those that require a separate room to house the equipment. A few minutes measuring space can save considerable grief when it comes time to install. By the way, practically all systems need a solid, grounded, 110-volt electric power supply. If you have deficiencies in your electrical system they will probably have to be fixed. Computers tend to be sensitive to such problems.

Telephone lines: Many computer systems are dependent upon telephone lines to link a pharmacy with a central computer somewhere else. This may give you access to more information which is generally useful

(continued on page 9)

# "I choose a product because of..."



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No wonder nearly five generations of pharmacists have depended on



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Dista Products Company Division of Eli Lilly and Company Indianapolis, Indiana 46206 (continued from page 7)

to all of the company's clients. The disadvantages are in the time that it takes to transmit information and in the possibility of telephone line failure. If you are in an area that is known for telephone problems, special care is appropriate.

Service: There are a large variety of service arrangements available in the computer field. There are freelance service agents, there are people who work for the manufacturer of the hardware, and there are those who both make and service what they sell. Each has advantages and disadvantages. This is also an area in which unexpected costs can develop. At this point you may also wish to consider the big-v.-small question: the large corporation or the small firm?

Appearance: It is important that the system you install looks good in your pharmacy. Yet so far, elegant styling seems to be designed for sit-down, office-type settings. Few pharmacies are set up that way; most do not even have the space for it.

Throughput: Can the system really handle your volume? The experience of other pharmacies, especially those with styles of practice similar to yours, is important.

System Capacity: Every computer has a limit to the amount of information it can keep in its active files. When this limit is reached, information must be removed or "purged" to make room for more. In evaluating the various systems you should determine what their capacities are, what is done when capacity is reached, and what they look like after the purge is done. In other words, how much does the system hold and what are the characteristics of purged information?

Codes: Computers deal in absolutes: everything is either black or white. Any grays are no more than combinations of blacks and whites. For this reason, it is easier to program computers to deal with numbers rather than names and many systems use codes or numbers for drugs, patients, doctors, and other data. Codes have the advantage of being clearcut, direct identifiers of something or

somebody to the computer. But they can be just the opposite for the computer operator. Codes must be looked up (except for those you have memorized) and must be entered precisely. Find out what the coding system is and exactly how to deal with it. You should avoid looking up things for the computer when it is supposed to be looking up things for you.

User Manual: Every system has a user's manual. Get copies of the manuals for the systems that look the best for your pharmacy. Take the time to read and understand them.

Legal Requirements: Each state has different legal requirements that may be applicable to pharmacy computer systems. In addition, the Drug Enforcement Administration has recently written some pretty strin-

#### THE GROUNDWORK

Lay a solid foundation for your computer system. Some cornerstones:

- ☐ Gather information on all of the systems that you think may be useful in your own pharmacy style of practice . . .
- ☐ Narrow down your choices to a manageable number, disregarding systems that offer too much or those that offer too little . . .
- ☐ Talk to others who have installed systems. You'll find out things about computers that only those who own one would know....
- ☐ Push the buttons on the systems that look good. Run demonstrations yourself and become familiar with each . . .
- ☐ Prepare your staff. You'll find that people who are threatened by the presence of computers are on shaky ground anyway.

gent rules regarding computer storage of information relating to controlled drugs. Another factor to consider along the same lines is what would Medicaid require regarding data retrieval? Obviously, it is important that any system you are seriously considering should not get you into any legal problems.

Data Security: It is appropriate to ask who will have access to your prescription files. If the information in your files is to be used for any purpose other than meeting your pharmacy's needs, be sure that such use meets your ethical and legal requirements.

**Data Loss:** It is possible to lose data because of mechanical or electrical failure, as well as through operator or programming errors. Inquire about backup mechanisms that will provide recovery from such problems.

Contracts: Read contracts carefully. Get the fine print explained. It is especially important that the paragraphs about discontinuing the system, for whatever reason, be clear regarding ownership of the files and who is responsible for what. Already, some serious disagreements have occurred over such matters.

Fees: Find out exactly what it is going to cost you to operate the system in your pharmacy. Be especially alert for costs that you may assume are included, such as telephone line charges, hardware service, paper, etc. Keep asking if there are any additional costs you should know about.

Along the same lines, carefully consider the virtues of owning v. renting computer equipment. Ownership may have some tax advantages that you should discuss with your accountant. On the other hand, renters don't have to worry about getting stuck with obsolete or difficult-to-service, or for other reasons unwanted equipment.

Cost-Benefit Analysis: When you hear what you are going to be charged for the computer, your response will be, "It costs too much." But, if it does half the things the salesperson said it would, it will save you money. List all of the functions it performs and put a price on each one. Decide how much a feature is worth to you, regardless of whether or not you have an immediate need for it. If it is something you are doing now, figure out how much it is really costing you. For example, many pharmacies are now spending many hours filing and finding profile cards. Time is money.

People: Getting to know people that you will be dealing with can be very helpful. Many of the people working with pharmacy computer systems have come up through the accounts-receivable ranks, where it is desirable, but not mandatory, to get the bills out on the right day. You

know your patients need their prescriptions today. Be confident that the organization providing your computer and service understands and appreciates your priorities.

Once you have decided to do it and which system you will do it with and probably after you have given some money to the computer company — the day will soon arrive when you actually get the system. Be sure you are well rested. People will arrive with lots of wires and equipment, which you may have seen before, but which still look strange in your pharmacy. They will probably be talking a foreign language that includes words like baud rates, modems, bits, bytes, boots, ICs, and interface boards. They will poke holes in your fixtures and string wires over and under your prescription counter. This may last for an hour or for several days, depending on the system and the inevitable miscellaneous little problems that pop up. Bear with them. They are just as anxious as you are to get the system up and working properly.

They should leave one person behind to help you get familiar with the day-to-day operation of the system. Make sure that person answers all of your questions and listen carefully to what he says. If you do not understand something completely, keep pursuing the point until you do. It is better to avoid costly errors than to have to correct them later.

Do not plan on putting all of your prescriptions through the new system the first day. Listen to the company's advice regarding how to best phase the system into your pharmacy. Without exception, everyone who has put a system in says that the first week is very trying, the first month is not easy, and at about the third or fourth month things really smooth out. Except in those cases where the system does not match the pharmacy's needs, after the fourth month it becomes an integral part of your practice and it becomes very difficult to function without it.

During the first few weeks, clerks, technicians, stockboys, and spouses need to be aware of your preoccupation, and maybe frustrations, in getting the thing to work right. Just remember that those who have gone before you are glad they did, for they now have a new and useful tool which is enabling them to do a better job faster and more accurately than was before possible.

Keep a "want-book" handy and label it "Computer Questions." Every time a little question occurs, note it on that pad. Experience has shown that there are a lot of little questions that come up that do not have to be answered right away, but usually end up forgotten when the person who can answer them is there. A phrase computer people frequently hear is, "I wish I could remember what I wanted to ask you."

Lastly a word of caution for the do-it-yourself types. There are a number of fascinating hobby computers that have the capability of meeting many of pharmacy's needs. "Having the capability" does not mean that it is easy to put them together and teach them all of the things they need to know in order to help you in the pharmacy. It will probably take several months of spare-time work before you have reached the point where your computer will play a decent game of tic-tac-toe. One can imagine how long it will be before it can cope with Medicaid and DEA rules.

**BE CAUTIOUS:** Avoid getting stuck with a system that you *hope* will do what you want it to do. Get one that *does* what you want it to do.

Computers are not for everybody. Some pharmacies just do not have enough prescription activity to keep a pharmacist busy, much less keep a computer busy. Too, some people just don't get along with machines. However, computers can be featured in promotional efforts designed to demonstrate your pharmacy's modern, complete service. And, they

WORK SHEET Importance to me В C Patient profiles Interaction notification Allergy notification Warning notices Label printing Pricing Medicaid billing Other third parties Controlled drug system Accounts receivable Management reports Output mechanism Hardware Space Telephone lines Service Appearance Throughput System capacity Codes (or lack of) User manual Legal requirements Data security Data loss Contract Fees Cost benefit People

The work sheet is designed to provide a way to organize your thoughts and opinions regarding what you want and what the various systems have. Rate each function from 0 to 10. In the first column the rating represents how much you are interested in each feature; in the others it represents how well each system delivers.

are much easier to operate than you may expect.

The decisions that you make are important both financially and professionally. You will be committing yourself to spending hundreds of dollars each month. And you will be setting a professional course for your pharmacy that will significantly affect your style of practice and the level of service your patients receive. The time and money you invest in the decision should be proportionate to its significance.

(The foregoing article has been reprinted with permission from the *California Pharmacist*, Sept. 1977, pp. 21-25.)

If you're confused about computers but think that you may be ready for one in your practice, Computers for Pharmacy was written for you. In simple, straightforward language, this new APhA publication explains how computers work, what those strange sounding computer terms mean, what professional and business functions computers can perform for you, and the general kinds of systems now available. Computers for Pharmacy is an indispensable aid in making two important decisions—(1) whether or not computer technology is practical for your practice, and if so, (2) how you go about comparing and evaluating the growing number of systems that are commercially available. If you take the "big step" and install a system, this APhA publication will provide invaluable tips on making the transition, as well as "troubleshooting" problems if and when they occur. So obtain your copy today by completing the order form and take advantage of our special pre-publication offer. We don't need a computer to know Computers for Pharmacy makes good sense for

#### Sourcebook on Computers in Pharmacy Published by ASHP

A 300-page reference book on the use of computers in pharmacy has been published by the American Society of Hospital Pharmacists (ASHP).

The Sourcebook on Computers in Pharmacy, a compilation of 50 articles on the impact of computer technology on the distribution of drugs, is an ideal reference book for those involved in a computerized drug distribution system. Most of the articles included in the Sourcebook originally were published in the American Journal of Hospital Pharmacy.

Articles in the Sourcebook are divided into 10 sections. These are:

- \* Review of Computer Applications in Hospital Pharmacy
- \* Basic Computer Hardware and Software
- \* Drug Coding and Classification Systems
- \* Inventory Control and Accounting Applications
- \* Formulary and Drug List Applications
- \* Drug Interaction Surveillance Applications
- \* Patient Profile and Unit Dose System Applications
- \* Ambulatory Applications
- \* Drug Utilization Review Applications
- \* Special Applications

According to James P. Caro, ASHP Manager of Special Publications, the *Source-book* will be useful for pharmacists interested in establishing a computerized drug distribution system as well as for those who are expanding an existing system. "Information included in the *Sourcebook* was selected on the basis of its application to the actual use of computers in pharmacy departments," Caro said. "In that way, pharmacists can get a good idea not only of past accomplishments in computer technology but also of future trends developing in the field."

The Sourcebook is available for \$15 to ASHP members, \$20 to nonmembers. All orders must be prepaid. For further information, contact: ASHP, 4630 Montgomery Ave., Washington, D.C. 20014.

#### COMPUTERS PHARMACY American Pharmaceutical Association 2215 Constitution Ave., N.W. Washington, DC 20037 Please send me \_\_\_ \_ copies of Computers for Pharmacy at the special pre-publication rate \$7.00 for APhA members (\$11.00 for non-APhA members). Offer expires July 1, 1978. ☐ Bill me. ☐ Payment enclosed. Orders totaling less than \$50.00 must be prepaid or accompanied by purchase order. NAME ADDRESS \_STATE \_\_\_ Foreign orders must be prepaid. Quantity discount schedule available on request. APhA Members: To receive member rate, attach a mailing label from APhA Weekly or American Pharmacy. 780415 -------



### Report from the Board of Pharmacy

by
— Paul Freiman
Commissioner

Pharmacists and the public realize that a Board of Pharmacy exists in the state of Maryland. Unfortunately, what it does, who it is, what it can do, and what it is supposed to do remains a mystery to many. Hopefully, through the *Maryland Pharmacist*, the Board of Pharmacy can communicate with the pharmacists of Maryland so that any misunderstandings, misconceptions, or mis-information about the Board can be dealt with and solved. This column will appear monthly in this publication to inform you what we are attempting to accomplish.

The Maryland law states that the Board of Pharmacy shall consist of six members who shall be pharmacists, and one consumer or public member. All members of the Board are appointed by the Governor for a term of 5 years, and are known as Commissioners of the Board. Three of the Commissioners are community pharmacists, Ralph Quarles, President of the Board; Bernard Lachman, and Paul Freiman. Bob Snyder is a hospital pharmacist; Leonard DeMino, a chain pharmacist; Charles Tregoe, Chief division of drug control, and Estelle Cohen, the consumer member completes the membership of the Board.

According to law, the duty of the Board is very specific. It will receive applications for examination and registration, and grant licensure under the law. It will report annually to the Governor, Secretary of Health and Mental Hygiene, and the Maryland Pharmaceutical Association on the condition of Pharmacy in Maryland, and it will keep a book in which shall be kept names of all registrants in our state. In addition the Board has the power to adopt rules and by-laws necessary to the transaction of the business of the Board, receive fees and payments, and promulgate rules and regulations under the Administrative Procedure Act. The Board has the power to reprimand or revoke a Pharmacist's license, under very specific conditions, as stated in Maryland law.

Unfortunately, the Board is often criticized by many Pharmacists for not doing enough for Pharmacy or for Pharmacists. However, by oath, the members of the Board are directed to serve the interests of all the people of Maryland, and insure the public that they will receive the best pharmaceutical service possible. We are receptive, however, to the problems of pharmacists, and can be reached by phoning 383-7245, if you feel that there is a situation that the Board should be aware of. In addition,

our meetings are held on the third Wednesday of each month, at the state office building, and are open to all the public. If you would like to attend a meeting, of ir you have something to be added to our agenda, please call the Board.

At the Board meeting held on March 15, 1978, the board discussed the progress of legislation concerning Pharmacy and the Board, including the continuing education bill, pharmacy discipline bill and other pertinent legislation. At this time most bills are still in committee, and will be reported on at the next meeting.

The Board expressed its impatience with the delay in release of the Formulary of acceptable drugs under the Drug Product Selection Law. It is hoped that the formulary will be out shortly, so that Pharmacists in Maryland will be able to utilize the law. In the case of P. Paul Weiner vs. I. E. Kerpelman, we were informed that the judge ruled that the law requiring posting is constitutional, and thus pharmacies will be required at this time to continue posting of prices as specified in the law. An opinion was also received from the Attorney General, that the Board could not issue a permit as a hospital pharmacy to the University of Maryland — Student Health Center, since it did not qualify as a hospital pharmacy under the law.

The final draft of the Proposed Institutional Pharmacy Regulations were presented to the Board for approval. The next step will be to publish the proposed regulations in the Maryland Register and set a hearing date. Mrs. Cohen expressed concern about manufacturers' labeling of drugs. She was advised that Maryland law requires the original manufacturer's name on the label, and if anyone knows of cases where this is not being done, they should inform the Board for action. Other business included correspondence with the NABP, the answering of a consumer complaint, reports from a pharmacist on probation, and the request from the Baltimore City Jail for an inspection of their Pharmacy for licensure.

Hopefully, the next report appearing in this journal will not be nearly as lengthy. I did feel it was important to clear up any misunderstanding about the role and function of the Board. If you have any questions or feel some changes should be made to make the Board more responsive, please call 383-7245. The Board is meant to serve all the citizens of Maryland and that includes you.

## National Employment Service for Pharmacists

A year-round national employment service for pharmacists will be launched following the 1978 Annual Meeting of the American Pharmaceutical Association in Montreal, May 13-18.

This National Registry for Pharmacists to be operated by the Illinois State Job Service and APhA is a centralized nationwide clearinghouse for employers and employees. The program is an extension of the Professional Placement Service which has been offered at APhA Annual Meetings since 1963.

Pharmacists seeking employment will complete an "Employee Application Form" describing their education, licensure, practice experience, and type of position desired. Employers will complete an "Employer Order Form" describing vacancies and requirements. There is no placement fee for this service and it is open to all pharmacists as well as all employers seeking to employ pharmacists and pharmaceutical scientists. Classifications include community practice, institutional practice, industry, education, and government.

Copies of all applications meeting employer's selection criteria are forwarded by the National Registry to employers to allow the employer to contact the applicant directly. The National Registry for Pharmacists does not distribute vacancy lists, nor does it make any recommendations.

For copies of the "Employee Application Form" and/or the "Employer Order Form," write the National Registry for Pharmacists, 40 West Adams Street, 9th Floor, Chicago, IL 60603, or APhA Division of Communications, 2215 Constitution Avenue, N.W., Washington, DC 20037. All completed forms are to be returned directly to the National Registry for Pharmacists.

The Maryland Pharmaceutical Association offers a free employment placement service to its members as a free benefit. The Association staff will attempt to match pharmacist with job openings. This service is operated in coordination with the University of Maryland School of Pharmacy placement service.

In addition, the classified advertisement section of the *Maryland Pharmacist* occasionally carries opportunities for employment.

For additional information on these services, contact the MPhA Office at 650 West Lombard St., Baltimore, Md. 21201 (301) 727-0746.

### A Preview of Community Pharmacy 1978

This year's preliminary *Lilly Digest* report, based on 1977 operating statistics from 872 community pharmacy operations, indicates an ever-higher cost of goods sold, with further decline in net profit. The data suggest that stronger effort must now be exerted to "hold the line" on operating costs. When the income and expense statement items are expressed as *percentages of total sales* and compared with *Lilly Digest* figures for 1976, they show that . . .

The cost of goods sold has increased, and although total expenses decreased somewhat, it was not enough to prevent net profit before taxes from dropping to 3.5 percent of sales.

Total sales reached a new high of \$325,656 — \$15,931 (5.1 percent) over 1976 sales. This rate of increase, however, is lower than the average annual growth rate of 6.4 percent observed during the past ten years. Prescription sales continued to outdistance other sales by showing an 8.0 percent gain in contrast to a 2.3 percent increase in other sales. Total prescription sales accounted for over half of the community pharmacy volume at 51.0 percent of sales (up from 49.6 percent in 1976). This illustrates the dominant position the prescription department maintains in the financial picture of the average community pharmacy.

The greater cost of goods sold forced the gross margin down again to 34.9 percent of sales (down from 35.1 percent in 1976).

Total operating expenses rose by \$4,392 (4.5 percent) but, as a percentage of sales, fell slightly to 31.4 percent. Employees' wages increased in dollars but remained constant at 11.8 percent of sales. The average proprietor's salary was lower both in dollars (by \$194) and as a percent of sales (6.9 percent — down from 7.3 percent). Although net profit declined as a percent of total sales, it was \$491 higher (up 4.5 percent over 1976). This allowed total income (salary plus net profit, before taxes) to increase slightly in terms of dollars but to drop sharply from 10.9 to 10.4 percent in 1977.

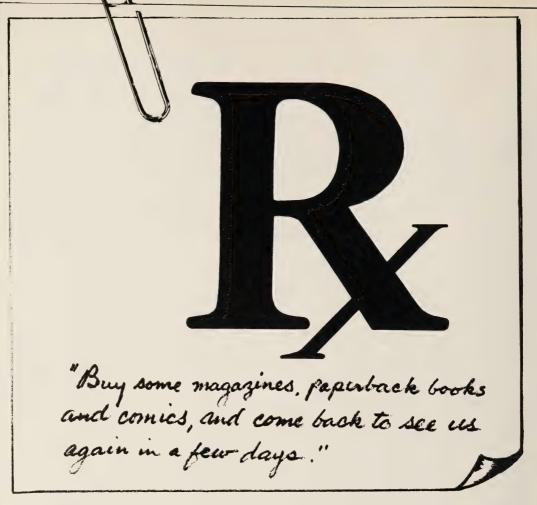
Although prescription inventory required more dollars, it declined percentagewise, while other merchandise inventory increased in both respects. This caused the prescription department's sales productivity to move up slightly to \$8.32 per stock dollar (0.4 percent higher), whereas other merchandise productivity decreased from \$4.81 to \$4.70.

The share of new prescriptions continued to grow. The number of new prescriptions increased by 626 (up 4.9 percent over 1976), while refills were 103 under last year's figure. As a result, the total number dispensed was 27,686, a gain of 523 prescriptions. Since this reverses the past two years' prescription trend, it will be interesting to see whether the final 1977 operating statistics show a similar increase. The average prescription charge went up to \$6.00 during 1977, up 34 cents from \$5.66.

The following table summarizes the preliminary *Lilly Digest* report of the 1977 operating figures of 872 community pharmacies and compares these with the 1976 *Lilly Digest* averages from 1,705 pharmacies. The annual *Lilly Digest* will be completed and distributed in September, 1978.

#### LILLY DIGEST PRELIMINARY REPORT — 1978

Averages per Pharmacy	1977 (872 Pharmacies)	1976 (1,705 Pharmacies)	Amount and Percent of Change
Sales			
Prescription		\$153,735 — 49.6% 155,990 — 50.4%	+\$12,297 — 8.0% +\$ 3,634 — 2.3%
Total		\$309,725 — 100.0%	+\$15,931 — 5.1%
Cost of goods sold	211,919 — 65.1%	200,871 — 64.9%	+\$11,048 5.5%
Gross margin		\$108,854 — 35.1%	+\$ 4,883 — 4.5%
Expenses			
Proprietor's or manager's salary	¢ 22.402 6.09/	\$ 22.597 — 7.3%	(-\$ 194 — 0.8%)
Employees' wages	38.545 — 11.8%	36,417 — 11.8%	+\$ 2,128 — 5.8%
Rent	8,120 — 2.5%	7,758 — 2.5%	+\$ 362 — 4.7%
Miscellaneous operating costs	33 168 — 10 2%	31,072 — 9.9%	+\$ 2.096 — 2.1%
Total expenses	\$102,236 — 31.4%	\$ 97.844 — 31.5%	+\$ 4,392 — 4.5%
	\$ 11,501 — 3.5%	\$ 11,010 — 3.6%	+\$ 491 — 4.5%
Net profit (before taxes)  Total income (net profit plus	\$ 11,501 — 5.5%	φ 11,010 — 3.070	1ψ 401 4.070
proprietor's salary, before taxes)	\$ 33,904 — 10.4%	\$ 33,607 — 10.9%	+\$ 297 — 0.9%
Value of inventory at cost and as a percent of sales			
Prescription		\$ 18,554 — 12.1%	+\$ 1,392 — 7.5%
Other		32,454 — 20.8%	+\$ 1,516 — 4.7%
Total	\$ 53,916 — 16.6%	\$ 51,008 — 16.5% 	+\$ 2,908 — 5.7%
Annual rate of turnover of inventory	4.0 times	4.1 times	
Number of prescriptions dispensed			
New		12,860 — 47.3%	+ 626 — 4.9%
Renewed	14,200 — 51.3%	14,303 — 52.7%	(- 103 — 0.7%)
Total	27,686 — 100.0%	27,163 — 100.0%	+ 523 — 1.9%
		\$ 5.66	+\$ 0.34 6.0%



That's the prescription you can fill again and again for your customers if you have a fully stocked magazine department.

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CIBA

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Stock with assurance.
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Geigy Pharmaceuticals shall indemnify and hold harmless any pharmacist, or his employer, against any product liability suit arising as a result of the pharmacist dispensing a Geigy product. This indemnification shall include the payment by Geigy Pharmaceuticals of all reasonable expenses and attorneys' fees incurred by the pharmacist, or his

employer, in connection with said law suit, and the assumption by **Geigy** Pharmaceuticals, where appropriate, of the defense of the action through its own attorneys.

This agreement by **Geigy** Pharmaceuticals to indemnify and hold harmless, as set forth above, is expressly conditioned upon the pharmacist, or his employer, immediately notifying the Company of any claim, demand, or the service of any complaint. This



# nd every pharmacist who dispenses it.

deement is further expressly additioned on the pharmacist, nis employer, providing full aperation to the Company, inding complete access to all evant records, and on Geigy armaceuticals having complete atrol over the conduct and dissistion of any claim, demand, aw suit.

This agreement is not applicable if **Geigy** Pharmaceuticals determines that there is evidence of any improper or negligent statement or act, or omission to act, by the pharmacist, or his employer, or if **Geigy** Pharmaceuticals determines that there is evidence that the product has not been properly stored or properly dispensed.

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# Liability Protection (It comes with every tablet you dispense)

A recent article on pharmacy law stated that "it is not unlikely that pharmacists substituting therapeutically or bioequivalent drugs for those prescribed will face increasing confrontation in the courts on the issue of their liability for unanticipated or ad-

verse reactions from drugs dispensed by them."\*

It should be reassuring to know, therefore, that McNeil Laboratories stands

behind you every time that you fill a prescription for TYLENOL® with Codeine tablets or elixir—and, for that matter, for every McNeil product you dispense. The "McNeil Pharmacist Protection Policy" gives you this assurance. (If you don't already have a

> copy, you might like to send for one.)

With the many problems facing the pharmacist today, why risk unnecessary liability problems.

\*From a special report reprinted from U.S. Pharmacist 2(4):18-23, 1977: "Pharmacy Law," by Michael R. Sonnenreich, J.D.



Dispense with confidence...Dispense the leader

# Phosphorus Prescribing in Total Parenteral Nutrition (TPN) Therapy

Phosphorus, in the form of organic and inorganic phosphates, is responsible for the synthesis of high energy phosphates, the production of erythrocyte adenosine triphosphate (ATP) and 2, 3 diphosphyoglycerate (DGP), and the maintenance of red cell glucose utilization (1). Hypophosphatemia manifests itself with weakness, malaise, bone pain, arthralgia, and ultimate osteomalacia (2). Acute hemolytic anemia and impaired tissue oxygenation can occur in severe hypophosphatemia. TPN therapy can induce hypophosphatemia if sufficient phosphate is not supplied. Travasol 8.5 percent® (Travenol Laboratories) is now the basic crystalline amino acid solution supplied by the Department of Pharmacy Services. It should be noted that Travasol 8.5 percent® does not contain phosphorus; the only electrolytes present are acetate (52 mEq/liter) and chloride (34 mEq/liter).

Phosphorus is supplied by adding potassium phosphate to the TPN infusate. The commercial preparations of potassium phosphate are mixtures of monobasic and dibasic phosphate salts. Upon dissocation, the ultimate monovalent and diavalent forms of phosphate are dependent upon pH conditions. In order to accurately determine the amount of phosphorus present in terms of milliequivalents, it would be necessary to determine the pH of its environment. Therefore, it is inappropriate to order phosphorus in terms of mEq. potassium phosphate. To avoid confusion, desired phosphorus should be expressed in millimoles (a millimole is the molecular weight of a substance expressed in milligrams).

The average adult requires 10-15 millimoles of phosphorus daily. The hypermetabolic or severely traumatized patient receiving TPN therapy may require 10-12 millimoles of phosphorus per liter of 25 percent glucose-based hyperalimentation fluid (1). Renal function must be assessed before prescribing phosphorus. Also, the prescriber should be aware of the reciprocal relationship between serum calcium and phosphate concentrations. The amount of phosphorus prescribed should be 1.5 times the calcium infusion.

Due to the wide variation in the formulation of commercial potassium phosphate injections, the Department of Pharmacy Services requests that all orders for phosphorus supplements in TPN solutions be expressed in millimoles.

# **Intravenous Potassium Phosphate Dosage Forms**

Manufacturer	Conc./MI.	Mg. elemental phosphorus/ml.	
*Abbott	P 3.0 m K 4.4 m		
Baxter	P 2.15 r K 3.0 m		
McGaw	P 1.12 r K 2.0 m		

\*Presently utilized by the Department of Pharmacy Services

#### References

- 1. Turco, S.J. and Burke, W.A.: Methods of Ordering and Use of Intravenous Phosphate. *Hosp. Pharm.* 10: 320-326 (1975).
- Bowman, J.: Phosphate Therapy. The University of Alabama, Drug Information Bulletin. Vol. 11, January, 1977.

# I.V. Infusion Pumps

All Abbott/Shaw Life Care® Model I infusion pumps have been replaced with the Model II series. The new pump operates in the same manner as the original pump with one major exception: After priming the set, the white plunger on the pump chamber must now be pulled up before the pump chamber is inserted into the pump receptacle. When the white plunger is pulled up the fluid-flow through the set is stopped, even though the pump is set on the 'open' position. No fluid will flow through the line, even with both clamps full open. To convert the system to gravity flow the pump chamber must be removed from the pump chamber receptacle and the white plunger on the top of the pump chamber pushed in.



May 4 (Thurs.) — MPhA Board of Trustees Meeting May 9 (Tues.) — Alumni Association Annual Meeting — Elections

May 13-18 — MPhA Montreal Trip — APhA Meeting June 1 (Thurs.) — Alumni Association Banquet June 8-9 — Second Interprofessional Conference, U

of M, Baltimore June 16-18 — MSHP Seminar, Williamsburg

June 18-22 — MPhA Convention, Ocean City — Fun in the Sun at the Carousel

Sept. 17-21 — NARD Convention, New Orleans Oct. 29 (Sun.) — Alumni Association Oyster Roast If you think Purepac is a quality generic,

# You're Right!

If you think Purepac is expensive,

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Purepac's line of over 300 generics is one of the lowest priced brands available to pharmacists.

Sometimes, when comparing specific prices, you may find a Purepac generic costs you a fraction of a cent more per tablet or capsule than generics available from other sources.

Why does this fraction of a cent difference occur? Because Purepac spends more to protect your professional integrity. Purepac manufactures most of its major generics, provides product liability protection, has its own quality control laboratories and tests its products to insure you consistency in size, shape, color and product uniformity.

When assuming the responsibility of product selection, choose Purepac, because you get Purepac quality at the right price.

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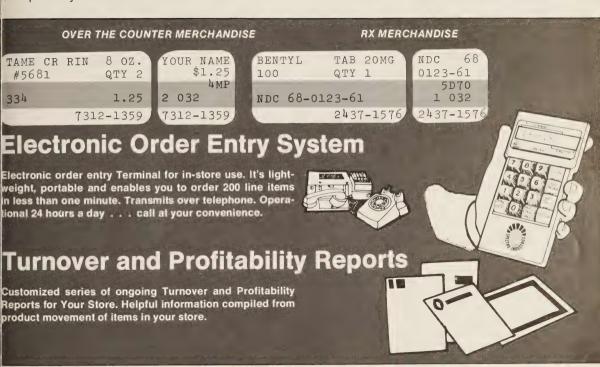
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- Ink Screening of Coded Information.
- Deal Contents Have Price Stickers.
- Price Stickers for Selected Full Cases.
- NDC Numbers on All RX Products.
- Customized Pricing.
- Two Price System.

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LOFWY DRUG CO. 6801 QUAD AVENUE, BALTIMORE, MD. 21237 YES, I'd like to get more FACTS ABOUT SPACE:

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TITLE

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# **Maryland Pharmaceutical Representatives**

The Industry Relations Committee of the MPhA recently conducted a survey of PMA member companies to compile a list of Sales Representatives who have some territory within the state of Maryland. Of the 83 companies contacted, 38 did not reply. Association members may wish to save this list for reference and update information as necessary.

# Abbott Labs

Carl W. Rappold 9123 North Naygall Road Baltimore, Md. 21234 301-256-5563

Mr. Andrew C. Thompson R.D. #2, 15 Skycrest Landenberg, Pa. 19350 215-274-8713

#### Alcon Labs

Vern Errickson 634 Wendy Circle Berwyn, Pa. 19312 215-644-6285

# Allergan

Jerry Nielson 2394 Whittier Ave. Westfield, New Jersey 07090 201-232-6671

Andy Berger 356 Margery Road Yardley, Pennsylvania 19067 215-493-1258

# Ames Company

William Cleaver III 3101 Plymouth Place Mechanicsville, Va. 23111 804-746-4598

# Armour Pharmaceutical Co.

Frank Campione 2226 Loch Lomond Drive Vienna, Va. 22180 703-281-4328

# Astra Pharmaceutical Products, Inc.

Joseph Boudreau 11436 Waterview Cluster Reston, Va. 22090 703-437-5848

# **Beecham Laboratories**

Caleb Myer, Jr. 1370 Halstead Road Baltimore, Md. 21234

# Burroughs Wellcome Co.

A. B. Credle 102 South Fox Rd. Sterling, Va. 22170 703-430-7336

# Ciba Pharmaceutical Co.

Thomas E. Boughton 3033 Arrow Head Lane Plymouth Township Norristown, Pa. 19403 215-828-3364

# Cooper Laboratories

David Leshine 710 Edgehill Drive Bel Air, Md. 21014 301-838-1117

# **Dorsey Laboratories**

E. A. J. Vittone 1012 Carol Drive Bridgeville, Pa. 15017 412-941-4848

A. L. Fox 7830 Mulberry Bottom Lane Springfield, Va. 22153 703-451-7545

# Dow Chemical

Joseph E. Hepp, Jr. Box 350 Morrestown, N.J. 08057 215-635-2762

# **Eaton Pharmaceuticals**

Edward G. Berlett 911 Pine Trail Bayberry-on-the-Magothy Arnold, Md. 21012 301-974-1392

# Endo Laboratories, Inc.

Jerry Hollerbach 183 Doncaster Road Arnold, Md. 21012 301-647-2090

# Geigy Pharmaceuticals

John H. Steighner Hidden Hill Road, R.D. #8 York, Pa. 17403

#### Hyland

Jack T. Kizer 1627 Withmere Way Dunwoody, Georgia 30338

Ed H. Henry 20040 Doolittle Street Gaithersburg, Md. 20760 301-977-8414

#### Ivers-Lee

Randy Anderson 147 Clinton Road West Caldwell, N.J. 07006 201-575-9000

# Ives Laboratories

George Melillo 2144 George St. North Huntington, Pa. 15642 412-864-5642

D. Kenton Berchtold Rt. # 3, Box 169, Larch Lane Middletown, Md. 21769 301-371-6657

# Knoll Pharmaceutical Co.

John G. O'Toole 955 Gladys Avenue Pittsburgh, Pa. 15216 412-561-8254

# Lederle Laboratories

Raymond R. Dalbke 2802 Page Court Fallston, Md. 21047

Howard W. Vanderbilt 10820 James Halley Drive Fairfax, Va. 22032

# Eli Lilly and Co.

R. M. Burget Suite 817 The Investment Bldg. One Investment Bldg. Towson, Md. 21204 301-823-2242

L. G. Holliman Suite 1200 Executive Bldg. 1030-15th St., N.W. Washington, D.C. 20005 202-296-2575

# McGaw Laboratories

John Odne 769 Northfield Ave. Suite 250 West Orange, N.J. 07052 201-731-6060

# McNeil Laboratories

Donald D. Horrocks 215-699-4813, 4814

# Mallinckrodt, Inc.

Calvin L. Jackson 1418 Francke Ave., P.O. Box 254 Lutherville, Md. 21039

#### Mead Johnson Pharmaceutical Division

Kenneth C. Gilbert 2214 Marbor Terrace Alexandria, Va. 22308 703-780-1452

# Ortho Pharmaceutical Corp.

Suite 218
11800 Sunrise Valley Drive
Reston, Va. 22091
Michael L. Connaway
Suite 604
Sinclair Bldg.
4th & Market Streets

Steubenville Ohio 43952

Reston International Center

# Pennwalt Corporation

Larry A. Johnson P.O. Box 2764 Lehigh Valley, Pa. 18001 215-866-5788

Mrs. Helen K. Wiggins 4209 Main Street Alexandria, Va. 22309 703-780-0371

# Pfizer Pharmaceuticals

Gary Todd 1223 Beechnut Court Woodbridge, Va. 22192 703-491-6221

# Roerig Division of Pfizer Pharmaceuticals

Bob Mangone 1595 Eton Way Crofton, Md. 21114 301-261-3983

# Pfipharmecs Division of Pfizer Pharm.

Paul F. Greenberg 98 Miles Standish Drive Marlboro, Mass. 01752 617-481-3936

# Pharmacia Laboratories

Earl Aversano 226 Sunny Jim Drive Medford, New Jersey 08055

# Purdue Frederick Co.

Seymour Rothman 1937 W. Cliff Drive Cherry Hill, N.J. 08003 609-424-4174

# Reed & Carnick Pharmaceuticals

Michael Morse 504 Beards Hill Road Aberdeen, Md. 21001 301-273-6652

# William H. Rorer, Inc.

Foster A. Tull 1003 Via Amorosa Campus Green Arnold, Md. 21002 301-647-9468

# **Model Return Goods Policy**

The Industry Relations Committee of the Maryland Pharmaceutical Association formed a subcommittee to study the issue of a Model Return Goods Policy. It was the feeling of the Committee, which is made up of manufacturing representatives and practicing pharmacists, that the policy should be fairly comprehensive and yet, provide some guidance and consistency in this area. The goal of the Committee was to develop a policy which could be endorsed by the Association in an attempt to establish a standard and which would be acceptable to both manufacturers and retailers.

After considerable deliberation, the Industry Relations Committee accepted the report of the Subcommittee which was subsequently adopted by the Board of Trustees of the Association at its regular meeting of April 6, 1978.

Part of the impetus for this project stems from the increased emphasis on the part of some state and federal regulatory agencies on the expiration dates of stocks within pharmacies. The Association is urging members to periodically check expiration dating and utilize the

Model Policy and proposed return goods letter to request authorization to return merchandise to manufacturers.

The Committee recommends that members retain this page from the journal and refer to the following MPhA adopted policy whenever a question concerning returning merchandise arises. In addition, the Industry Relations Committee serves as an ombudsman whenever members refer a problem concerning this subject in writing to it.

# MODEL RETURN GOODS POLICY

- New prescription drug products shipped to the pharmacy automatically by the manufacturer or wholesaler may be returned at any time for credit or exchange.
- Regardless of expiration dates products may be returned for credit or exchange at any time, providing they are sealed, intact, original packages.
- For patient protection, open packages of prescription drug products which are outdated may be returned for at least partial credit.
- Authority for returns may be required by the pharmaceutical manufacturer or wholesaler — a form should be provided to the pharmacy.

James D. Wilson 211 Hartranft Avenue — Coleston Norristown, Pa. 19401 215-272-2437

#### Sandoz Pharmaceuticals

William B. Russell 3314 Brantley Road Glenwood, Md. 21738 301-489-7290

#### **Schering Corporation**

Richard T. Muth 10834 Burbank Drive Potomac, Md. 20854 301-299-6790

#### Searle Laboratories

Michael V. Phillips 460 Maryleborn Road Severna Park, Md. 21146

#### Smith, Kline & French Labs.

Judith Woodward 710 McLean House 6800 Fleetwood Road McLean, Va. 22101 703-893-4430

Michael J. Peluse 472 Covered Bridge Road Cherry Hill, N.J. 08034 609-795-3232

# Squibb

Mel Kosko 1531 Crofton Pkwy. Crofton, Md. 21114

# Syntex Laboratories, Inc.

Jack Tuttle 11156 Conestoga Court Oakton, Virginia 22124 703-385-9198

# **Upjohn Company**

Robert L. Doolittle 402 Dreams Landing Way Annapolis, Md. 21401 301-269-6027 Lynn H. Ledden 9516 Falls Bridge Lane

Potomac, Md. 20854

## **USV** Laboratories

301-299-4820

Norman Walter 10004 Stedwick Road, Apt. 202 Gaithersburg, Md. 20760

#### Wallace Laboratories

Paul R. Katus 8020 Broad Lawn Drive Pittsburgh, Pa. 15237 412-366-9287

#### Warner Chilcott

Dave Wilbanks 5 Woodstone Court York, Pennsylvania 17402 717-757-5113

# Winthrop Laboratories

Richard A. Pingstock 393 Crescent Avenue Wyckoff, New Jersey 07481 201-891-0343

# SAMPLE FORM to Return Merchandise

TO: (Name of Manufacturer)

Address — including the name of Town, County,

State and Zip Code

(Note — the above as well as the policy for making returns may be located in the NWDA list of Mfgs. in January 1977 edition of the American Druggist Blue Book!

Please grant us authorization to return the following pharmaceuticals of your manufacture as per your policy:

It is best to list the items — listing complete packages as well as open containers. If a return of a schedule 2 is requested, be sure to give exact count and hold these aside as they usually will send a narcotic form. (Because of mail rates, it may be less expensive to have the drug inspectors destroy them.)

Note — If in their reply, they say they do not accept open containers — or — partially filled ones, call their attention to the fact that for the protection of the patient, as well as the pharmacist and the manufacturer, you believe it best they change their policy to permit them to accept them for credit.

# Alumni Association Graduation Banquet

The Alumni Association of the University of Maryland School of Pharmacy will hold its 52nd graduation and installation banquet at Martin's Eudowood Gardens, Towson on Thursday, June 1st, 1978.

One of the highlights of the evening will be the presentation of 50 year certificates to the Class of '28 and also presentation of the Honored Alumnus Award of 1978

Cocktails 6:00 p.m.

Tickets: \$13.50 per person

All information regarding tickets can be obtained by calling 675-6046.

Mr. William Weiner, Vice President of Calvert Drug, is the president of the Alumni Association.

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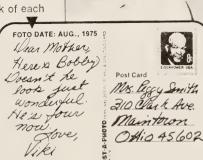
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# Gerry Hietala, Abbott research pharmacist, on flavoring:

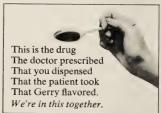
"One 'yuck' from any of these panel members and it's back to the drawing board. This is the final, most critical test for flavoring in our suspensions. No matter how much effort goes into the flavoring system of a pediatric drug, this is the bottom line. Kids simply won't take a bad-tasting medicine.

There are two basic objectives in flavoring a suspension; first, naturally, you want to mask the drug taste. Erythromycin is a prime example. It's bitter. Second, you want to maximize flavor stability. Over a period of time even insoluable drugs will hydrolyze to a limited extent. The flavoring must

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MPhA Convention



Ocean City, Maryland June 18-22, 1978

rogram .	At A	Glance
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SUNDAY June 18

9:30 p.m.

Registration open at 12:00 Noon (rooms available 3:00 p.m.)

Tennis, Golf, Swimming and Ice Skating Welcome Cocktail Party and Ice Show

MONDAY June 19 9:30 a.m. to Open General Session

House of Delegates — First Session

Officers' Reports

LAMPA — Brunch, Meeting and Fashion Show

TAMPA — Annual Meeting

6:30 p.m.

Crabfeast and chicken at Berlin Fire Hall TAMPA Program — Square Dance



TUESDAY June 20

9:00 a.m. to House of Delegates — Second Session Election of Nominees to Board of Pharmacy

Nomination of Officers and Trustees for Mail Ballot

LAMPA Board Meeting

6:00 p.m.

Cocktail Party — Annual MPhA Banquet awards and installation of officers

with special program



WEDNESDAY June 21 9:00 a.m. to "Understanding Common Gynecological Problems"

C. E. Program Sponsored by Lederle

Anatomy and physiology of the female Genitourinary system — Feminine Hygiene — Non-Prescription products

Contraception

The Pharmacist's role in managing the gynecologic patient

**Evening Cocktail Party** 



THURSDAY June 22 9:00 a.m. to 11:00 a.m. Simon Solomon Seminar on Pharmacy Economics

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# Case Study on Rx Refills

Reprinted with permission of the American Society of Pharmacy Law Rx lpsa Loquitur, March 1978

In June of 1971, a female patient of the pharmacist consulted her physician and obtained a prescription for Aristocort tablets. She presented the original prescription, which bore no instructions regarding refills, to the pharmacist and he gave her the prescribed medication. She continued as a patient of the physician and also continued to have the pharmacist refill the prescription. The pharmacist-plaintiff refilled the prescription a number of times over a period of several years. He stated in an affidavit that he refilled the prescription because his patient and her husband told him on a number of occasions that "the doctor had verbally authorized me to fill the prescription through her."

The patient later filed a lawsuit against her doctor and the pharmaicst to recover damages for personal injuries allegedly caused by their negligence and malpractice. The physician, seeking indemnification, cross-claimed against the pharmacist-plaintiff. The pharmacist in turn forwarded the summons and complaint to his insurer. The insurance company disclaimed liability and refused to defend the pharmacist against his patient's action or the doctor's cross-claim. It was the position of the insurer that the policy did not apply to bodily injury caused by the insured's willful violation of a penal statute.

Because of the insurance company's disclaimer, the pharmacist-plaintiff was forced to commence the present action against his insurer for a judgment declaring that it was obligated, under the policy, to defend him against both his patient's action and the physician's cross-claim. The trial court granted a summary judgment in favor of the insurance company on the ground that the pharmacist's action came within the exclusionary clause in the policy. It was claimed that the pharmacist willfully violated the following statute:

An oral authorization for the refill of a prescription, other than a prescription for a depressant or stimulant drug or narcotic, may be made by a practitioner legally authorized to prescribe drugs. The pharmacist receiving the oral authorization for a refill of a prescription shall write on the reverse side of the original prescription the date, time, and name of the practitioner authorizing the refill of the prescription.

The appellate court which was called upon to review

the lower court's decision found that the above statute is silent as to whether the physician's oral authorization must be made directly to the pharmacist or whether it may be made, as here, through an intermediary. The appellate court found that the pharmacist violated the statute by not writing the required information on the reverse side of the original prescription, but it held that this violation had no direct causal connection with the patient's injuries. The court found that her injuries were not caused by the pharmacist's violation of the penal statute, and therefore, the insurance company was obligated to defend the pharmacist in the lawsuit. Schwamb v. Fireman's Insurance Company of Newark, New Jersey, 383 N.Y.S.2d 52 (1976).

The insurance company sought further appeal in the Court of Appeals of New York. This appellate court also dealt with the issue of the insurer's obligation to defend the pharmacist in a third-party action brought by one of his patients. The Court of Appeals adds a new dimension to the controversy. It finds that the New York statute was not in effect the entire period during which the refills were dispensed. Because the refills did not all necessarily occur after the effective date of the statute on which the insurance company relied, the policy exclusion did not entirely preclude the alleged liability. In addition, the Court of Appeals also found that the complaint contained claims of traditional negligence based upon the pharmacist's alleged failure to inform or warn the patient. The court concluded "So long as the claims, even though predicated on debatable or even untenable theory, may rationally be said to fall within policy coverage, whatever may later prove to be the limits of the insurer's responsibility to pay, there is no doubt that it is obligated to defend." Therefore, the addition of claims outside the exclusionary clause of the policy required the insurance company to defend the suit. If these additional claims had not been included, there is strong evidence that the insurer would have been in a position to disclaim liability to defend, and the court would have supported such a position. It must be remembered that both of the appellate courts in this case are only addressing themselves to the obligation of the insurance company to defend. They are not rendering an opinion as to the actual merits of the action regarding the pharmacist's possible liability. Schwamb v. Fireman's Insurance Company of Newark, New Jersey, 363 N.E.2d 356 (1977).

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# Why do the overwhelming majority of physicians specify Librium? (chlordiazepoxide HCI)

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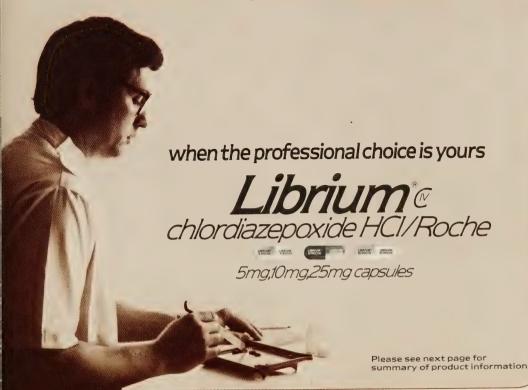
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Please consult complete product information, a summary of which follows:

Indications: Relief of anxiety and tension occurring alone or accompanying various disease states. Efficacy beyond four months not established by systematic clinical studies. Periodic reassessment of therapy recommended

Contraindications: Patients with known hypersensitivity to the drug

Warnings: Warn patients that mental and/or physical abilities required for tasks such as driving or operating machinery may be impaired, as may be mental alertness in children, and that concomitant use with alcohol or CNS depressants may have an additive effect. Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage: withdrawal symptoms (including convulsions), following discontinuation of the drug and similar to those seen with barbiturates, have been reported.

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (e.g., excitement, stimulation and acute rage) have been reported in psychiatric patients and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship has not been established

Adverse Reactions: Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction; changes in EEG patterns (low-voltage fast activity) may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making profracted therapy.

**Usual Daily Dosage:** Individualize for maximum beneficial effects. *Oral-Adults:* Mild and moderate anxiety and tension, 5 or 10 mg *t.i.d.* or *q.i.d.*, severe states, 20 or 25 mg *t.i.d.* or *q.i.d.*. Geriatric patients: 5 mg *b.i.d.* to *q.i.d.* (See Precautions.)

Supplied: Librium\*\* (chlordiazepoxide HCI) Capsules, 5 mg, 10 mg and 25 mg—bottles of 100 and 500; TeI-E-Dose\* packages of 100, available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10; Prescription Paks of 50, available singly and in trays of 10. Libritabs\* (chlordiazepoxide) Tablets, 5 mg, 10 mg and 25 mg—bottles of 100 and 500. With respect to clinical activity, capsules and tablets are indistinguishable



# Classified Ads



Classified ads are a complimentary service for members.

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Suitable for pharmacy. Ground floor next to Sinai Hospital. 2,000 sq. ft. Call Sid Singer, 768-3938.

# SAPhA Students Win Award

James M. Easom and Bonnie Levin, students at the University of Maryland School of Pharmacy have been selected as first award winners in the 12th Annual Student American Pharmaceutical Association Papers Review Forum. The Award was given for their paper: "An Activated Charcoal and Microcrystalline Cellulose, An In Vitro Evaluation." They will receive \$100. and an opportunity to present the paper at the APhA Convention in Montreal.



700 East Joppa Road Baltimore, Maryland 21204

The Maryland Pharmaceutical Association has recently endorsed a group major medical health insurance plan from Blue Cross/Blue Shield of Maryland. We are currently in an open enrollment period for members family and non-pharmacist employees of members. Contact the M.Ph.A. office or Blue Cross/Blue Shield for the details.

# LETTERS



Mr. David Banta Maryland Pharmaceutical Association 650 West Lombard Street Baltimore, Maryland 21201

It would be appreciated if you would put the following notice in the next issue of the Maryland Pharmacist

Thank you for your assistance.

# NOTICE

THE MARYLAND BOARD OF PHARMACY WILL CONDUCT AN EXAMINATION FOR REGISTRATION AS PHARMACIST AT THE UNIVERSITY OF MARYLAND IN BALTIMORE, MARYLAND ON JUNE 28, 29 AND 30, 1978. APPLICATIONS MUST BE IN THE OFFICE OF THE BOARD BY JUNE 9, 1978. FOR PARTICULARS APPLY TO:

Ralph T. Quarles, President Maryland Board of Pharmacy 201 West Preston Street Baltimore, Maryland 21201 Phone — 383-7245

Sincerely.

Ralph T. Quarles, President
MARYLAND BOARD OF PHARMACY

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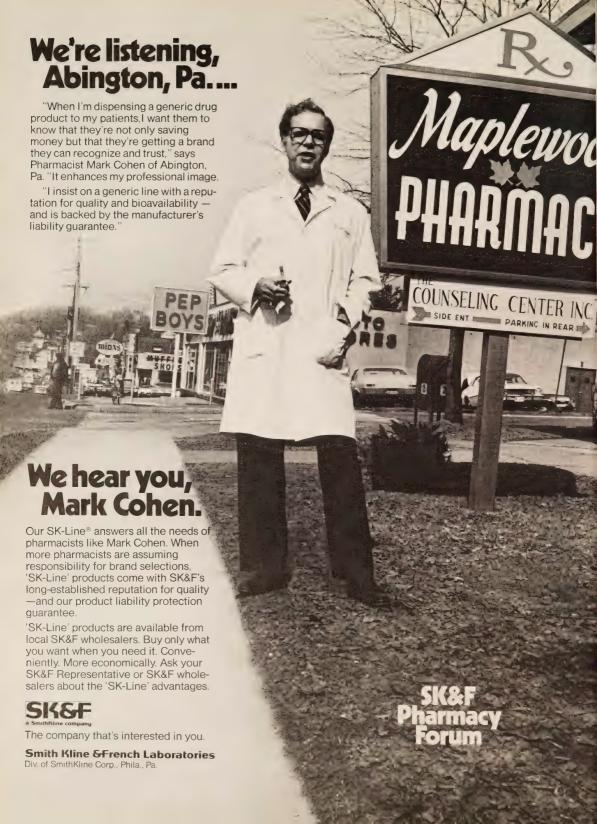
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Official Journal of The Maryland Pharmaceutical Association

JUNE, 1978 VOL. 54 NO. 6



# **Clinical Use of Tricyclic Antidepressants**

(with special self-evaluation quiz)

-Jerry A. Bennett, Pharm.D., R.Ph.

# Report from the Board of Pharmacy

.- Paul Freiman, Secretary

Maryland SAPhA News (Pictorial)

# THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET BALTIMORE MARYLAND 21201 TELEPHONE 301/727-0746

**JUNE 1978** 

**VOL. 54** 

NO. 6

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\*From a special report reprinted from U.S. Pharmacist 2(4):18-23, 1977: "Pharmacy Law," by Michael R. Sonnenreich, J.D.



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# PROFIT is the name of the game,

# but it's not the only game in town.

To some, the word profit is a dirty word. To others, it is a bit of nostalgia. It would appear the Federal government considers any attempt to secure profit to be illegal, underhanded, price-fixing, or some other nasty name. Certainly if two or more people get together to discuss how to obtain profit, the charge of restraint-of-trade, collusion, or gouging is leveled against the profession. Nevertheless, a profit is necessary for all phases of business, unless that business is subsidized by the government with our tax dollars. Manufacturers, distributors, and retailers must make a profit if they are to pay their employees a fair salary. This makes profit an incentive at all levels of our profession. Those who are interested in rendering the best health care, and there are ever increasing numbers of these professionals, realize that fee for service is a necessary part of every charge for a product.

The legislation presently before the Congress will drastically change some concepts of all health care delivery systems. It is not hard to see the future recognition of supportive personnel in pharmacy, identified through formal training as "Licensed Pharmacy Technicians." These assistants in our industry will no doubt replace the extra pharmacist on a shift and possibly even substitute on slow days. We can not allow any further intrusion of the government into the proper arena of professional schools and industry. Cost-containment will have us dispense only the lowest-cost generic drugs, using the least expensive "supportive personnel" available, and at the same time requiring mountains of paperwork and review

procedures. No one will profit, not even the public, though expecting a bargain.

Before the National Health Insurance program is introduced this fall, we have an opportunity to supply information on the proper method of providing pharmacy services. We have been invited to write to the deputy assistant secretary for health, Dr. James J. Mongan, Dept. Health, Education and Welfare, Washington, D.C. (736 Hubert H. Humphrey Blvd., Independence Ave. S.W.) to express our feelings and we should surely attach a fee for service in all that we do. While you are writing to Dr. Mongan, it would also be a good idea to write to your elected representatives to tell them how we have been subsidizing Medicaid and the other Third-Party Prescription Programs. Also it would be good to inform the patients, for whom we render such services, of the cost to us in providing the best health care delivery system in the world.

Again, I urge each pharmacist to support all professional associations who are attempting to represent us. Put your dollars to work in political action committees where the influence generated can do us all some good. Speak to your other health care professionals about our mutual problems and tell the media that we know what they can't seem to understand: profit cannot be generated by large volume sales

Silar of

at a loss. We cannot afford to play their game!

Richard D. Parker

# Clinical Use of Tricyclic Antidepressants

by

Jerry A. Bennett, Pharm.D., R.Ph.
Assistant Professor of Clinical
Pharmacy
University of Cincinnati
College of Pharmacy

Special Evaluation Quiz for this article — page 11

The use of the tricyclic antidepressants in the treatment of depressive disorders is now well established. These drugs along with their equivalent doses are listed in Table 1. They are effective agents in the treatment of endogenous depression. An endogenous depression is one which occurs without an obvious cause. The signs of endogenous depression are listed in Table 2. According to Hollister, endogenous depression is produced by a genetic inheritance or a biochemical defect.

Tricyclics are not indicated for reactive depression. In a reactive depression the causes which precipitate the depression can be clearly identified. Causes for reactive depression include loss of a friend, spouse, money, job or self esteem. The onset of therapeutic effects of the tricyclics takes several weeks and the reactive depression can often spontaneously remit within a month or two.

Aspects of endogenous depression which are lacking in reactive depression include: a family history of endogenous depression, periodicity of recurrences and a well defined course. The endogenous depression is a more severe condition with disturbances of basic body functions (sex, sleep, appetite, bowel action). The person suffering from endogenous depression has a greater chance of suicide than the reactive depressed patient.

Sometimes it is really difficult for the physician to differentiate between a reactive depression and an endogenous one. Skilled psychiatrists feel that when this situation does occur it is best treated with a tricyclic. If the patient suffers from an endogenous depression the proper treatment has been given. If the depression is really reactive no great harm has been done even though other drugs, such as small doses of some antipsychotics or antianxiety drugs may be equally effective or superior.

Proven indications for tricyclics include: involutional depression, the depressive phase of manic-depressive illness, psychotic depressive reaction and adjunct treatment for severe depressions in schizophrenia or organic brain syndrome. Involutional depression is a severe depression which occurs during the involutional period of

life. This is in the later 40's or early 50's for women and late 50's or early 60's for men. With this depression there is no history of previous depressive episodes. The depression which occurs in manic-depressive illness may alternate with the hyperactive manic state. A psychotic depressive reaction is a severe depression in which the patient has lost touch with reality.

No discussion on the applications of tricyclic antidepressants would be complete without covering the mechanism of action of these agents. The mechanism of therapeutic action remains hypothetical. As a class these drugs are potent inhibitors of the reuptake mechanism at the nerve terminal for norepinephrine and serotonin. The tricyclics potentiate and prolong the action of these biogenic amines (norepinephrine and serotonin) released by neurons in the brain. The amine hypotheis for depression is that a lack of the biogenic amines in the brain causes depression. Low levels of serotonin have been found in the brain of depressed patients who committed suicide. It has been found that patients treated with reserpine often develop endogenous-like depressions attributed to the reserpine depletion of biogenic amines.

Except for the more potent protriptyline and nortriptyline the usual therapeutic dose of a tricyclic antidepressant is approximately 150 mg per day (Table 1). This stated dose is at best an average figure because there is a considerable variation in the rate of metabolism of these drugs. With all tricyclic antidepressants studied so far the plasma concentrations obtained by patients receiving the same dosage of the drug have shown an impressive and consistent variation between individuals. Coyle has described a "therapeutic window" in which plasma levels of 50 to 200 mg per ml are the optimal antidepressant range. Plasma levels of drugs below and above this window are associated with poor clinical outcome.

Tricyclic antidepressant should be started at relatively low dose (25 mg two or three times a day) with an increase of 25 mg every few days as tolerated. The incremental dose is often best given at bedtime. When therapeutic doses are achieved a major portion of the total dose can be given at bedtime since the half-life of

these agents is sufficiently long for a single daily dose to maintain an adequate 24 hour plasma level. Some physicians will give the total dose at bedtime. This method focuses the acute, sedating side-effects of these agents at bedtime so additional sedatives are not required. Klein and Davis have long advocated the use of 300 mg per day as the point at which clinical failure can be assessed. The most common reason for therapeutic failure with the tricyclics in the hands of the general practitioner is too low a dose. In carefully selected patients the dose may be increased beyond what the company literature recommends.

The therapeutic response to these drugs is a gradual process with the rate of improvement inversely related to the severity of depression. The insomnia and anorexia may improve within a few days after therapeutic levels of the drug are achieved. The decreased interest and pessimism exhibit a more gradual and delayed response. It is much more useful to obtain information from family members or the nurse concerning the patients early response to antidepressant therapy because a delay in cognitive improvement may initially cloud the patient's appreciation of the amelioration of his somatic symptoms. After two to three weeks of antidepressant therapy the patient will continue to protest his terrible appetite and his inability to sleep whereas the nurse or spouse will describe considerable improvement.

Due to the time lag in responding and a large percentage of tricyclic treatment failures, several attempts have been made to enhance the effects of tricyclics. The use of triiodothyronine (T3, Cytomel®) with tricyclic antidepressants has received much attention in the literature. Several studies show that a two-week course of T3 at doses of 25 mcg per day in the female euthyroid enhance the therapeutic efficacy of tricyclics. This maneuver will sometimes shorten the initial time lag in response and convert non-responders to responders. The thyroid hormone may decrease the plasma binding of tricyclics so that more of the active free drug is available.

The side effects of the tricyclics are related to their actions of potentiating nonadrenergic transmission and blocking cholinergic receptors The common side effects of dry mouth, sedation and blurring of vision are generally mild but they should not lead to overlooking the serious toxic potential of these drugs. A 7 day prescription of tricyclics when ingested can be fatal. The adult lethal dose has been estimated to be 1000 mg. The pharmacist and physician should keep this in mind when dealing with the depressed patient who has suicidal possibilities.

The potent anti-cholinergic action of these drugs reduce salivary secretion producing a dry mouth. The use of sour candy and an increase in oral fluids will help correct this. The blurred vision may correct with a slight decrease in dosage. The more serious ophthalmic danger is pupillary dilation which can precipitate an acute glaucomatous crisis in the predisposed individual. Interference with parasympathetic function in the gut results in constipation which may be troublesome for the elderly. The judicious use of dioctyl sulfosuccinate can

	TABLE I	
	Tricyclic Antidepressar	nts
Generic Name	Trade Name	Average Therapeutic
Amitriptyline	Elavil	150
	Endep	150
Nortriptyline	Aventyl	100
Imipramine	Tofranil	150
	Presamine	150
	Imavate	. 150
	SK-Pramine	150
	Janimine	150
Desipramine	Norpramine	150
	Pertofrane	150
Protriptyline	Vivactil	40
Doxepin	Sinequan	150
	Adapin	150

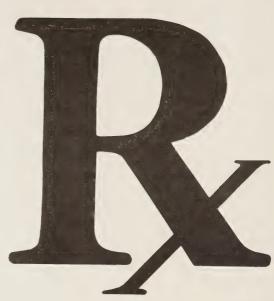
prevent tricyclic induced constipation. The tricyclics can cause difficulties in initiation of micturition. In elderly men with benign prostalic hypertrophy this side effect can precipitate acute urinary retention. The tricyclic antidepressant enhances the release of norepinephrine from peripheral sympathetics but the interaction of the drug at preganglionic sites often causes orthostatic hypotension. The patient can be taught to arise slowly from a sitting position and increase the daily oral intake to correct this. A drop of 15 to 20 mm in the systolic pressure is the usual decrease in this acute side effect which usually corrects itself in a week's time.

Tricyclic antidepressants have significant toxic effects on the heart including impaired conduction resulting in prolongation of the QRS interval and ST and T wave abnormalities on the EKG tracing. These effects usually occur at high doses but they have been observed in patients receiving an appropriate dose. These cardiovascular effects raise the question of which tricyclic antidepressant to use in the depressed cardiac patient. Ross has written that doxepin is the drug of choice for this problem but more studies are needed to confirm this.

Tricyclic antidepressants can also produce significant and sometimes confusing central side-effects. An atropine-like psychosis can be precipitated. Behavioral deterioration and confusion herald this serious sideeffect with a loss of orientation to place and time. The elderly are more prone to this side-effect.

Tricyclics can exacerbate schizophrenic psychosis or bring on a florid psychosis in a latent schizophrenic. The onset of schizophrenia occurs generally in the teens and twenties as compared to the later appearance of endogenous type depressions. The physician should be cautious about prescribing tricyclic antidepressants to young patients who exhibit symptons of withdrawal, psychotic thinking and depression since these can precede the schizophrenic reaction.

The various types of tricyclics shown in Tabel 1 present a problem to the physician when it comes to deciding which drug to use. Clinically they are all rather similar.



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On the basis of comparative studies little basis exists for preferring one drug to another in terms of overall degree of efficacy as judged by clinical comparisons between the various members. The choice of which antidepressant may depend on such factors as the availability of certain dosage forms, tolerance of the patient to sedative and anticholinergic actions and the prescriber's belief in important pharmacologic actions. Doxepin and amitriptyline are the most sedative of the tricyclics. Imipramine. nortriptyline and desipramine are a little less sedating. Protriptyline is the only tricyclic which may be viewed as possibly being a stimulant. This drug has been used in rare cases where the patient did not develop a tolerance to the sedating action of amitriptyline. The degrees of anticholinergic action are even more difficult to quantify. but amitriptyline, doxepin and impiramine are thought to have more of this action when compared to the other tricyclics.

As previously mentioned the pharmacologic action of the tricyclics is inhibiting the re-uptake mechanism for norepinephrine and serotinin at the nerve terminal. The re-uptake mechanism terminates the action of these biogenic amines. All tricyclics block the re-uptake mechanism but it is conspicuously weaker with doxepin. Theoretically it would not be a preferred choice for patients with endogenous depression. The tertiary amine tricyclics amitriptyline and imipramine are thought to block more selectively the uptake of serotonin than nonrepinephrine. Nortriptyline and desipramine block more selectively the uptake of norepinephrine than serotonin. It is uncertain which of the two biogenic amines is most important in depression or if there may be two major subcategories of depression based on neurotransmitter (norepinephrine, serotonin).

At one time parenteral administration of tricyclics was given some promotion but the clinical evidence that it speeded the time for recovery from depression was not convincing. The use of the pamoate salt of imipramine for single doses of drug to be given at night has no special advantage over using the hydrochloride salt of this drug or others.

The question of how long a patient should be maintained on tricyclic antidepressants is difficult because of a lack of data regarding the duration of treatment with these agents. Untreated depressive episodes are selflimiting and usually last for an average of six months to one year. The goal of drug treatment is to shorten the course of the depression and the drug should be continued for the duration of the natural course. If the first depressive episode responds quickly, tricyclic treatment can be tapered and stopped several weeks after remission. Continuous tricyclic therapy is indicated if the patient has had a history of multiple depressive episodes seen with depression-free periods. In the majority of cases, tricyclics should be used for each episode until the depression has resolved. After this the dose should be tapered to maintenance levels for six months to one year.

The abrupt withdrawal of tricyclics has been discouraged because symptoms from this can be produced. Stimmel describes these symptoms of insomnia, irritabil-

#### TABLE II

# Signs of Endogenous Depression

Decreased interest or ambition
Decreased response to environmental events
Loss of appetite

Loss of appetite

Disturbed sleep

Decreased response to interpersonal interactions

Constipation

Sadness, Tearfulness, Despair

ity, nausea, vomiting and generalized malaise in patients who have been treated with 150 mg of amitriptyline or its equivalent for two months or more. It is the personal opinion of this author that many physicians do abruptly discontinue tricyclics and these withdrawal symptoms are not seen.

Tricyclic antidepressants provide effective, relatively inexpensive somatic therapy for endogenous depression. They are not without risk but the hazards of tricyclic drug therapy are usually outweighed by the potential benefits.

(See Special Quiz - Page 11)

# National Drug Regulation Bill

In Washington, the Administration Drug Regulation Bill has finally been introduced. It is the first total overhaul of the nation's drug regulations in four decades. The new bill, commonly called "The Drug Regulation Reform Act of 1978," would make public experimental data on which drug approvals are based and could require patient package inserts for those drugs where the HEW Secretary deems information for consumers on benefits, risks, and side effects is nenessary. There are provisions of interest to pharmacists in this bill including retail price posting of prescription drugs designated by HEW after consultation with the Federal Trade Commission, a ban on state prohibitions of price posting, a requirement that the manufacturer's name and address be on labels of prescriptions and OTC drugs, as well as considerable more information on OTC labels. The bill would ban free samples by detailmen and gifts to pharmacists, physicians and others of more than a \$5.00 value. Another section of the bill would establish the National Center for Clinical Pharmacology which would research and make grants for research and training in clinical pharmacology including the education of physicians about drugs. Still another aspect of the bill would encourage physicians to prescribe drugs by their generic names. In order to aid this, the Federal Government proposes to require publication of a compendium containing the description of all drugs. The bill is quite lengthy. Anyone interested in having a copy of the full 228-page bill can obtain it at no charge by requesting a copy of S. 2755 from Senate Documents, Washington, D.C. 20510. Be sure to include a self-addressed, gummed label.



# Self Evaluation Quiz

# Clinical Use of Tricyclic **Antidepressants**

Jerry A. Bennett, Pharm, D., R.Ph.

1. The amine hypothesis of depression is that depression is due to an increase of amines in the brain

True or False?

- 2. Which of the following drugs is most likely to cause depression?
  - a) Hydrochlorthiazide
- c) Phenylbutazone
- b) Reservine
- d) Lithium Carbonate
- 3. Which of the tricyclics would be the best choice when amitriptyline has proven to be too sedating?
  - a) Endep
- d) Norpramine
- b) Aventyl
- e) Vivactil
- c) Tofranil
- 4. Klein and Davis recommend how many mg per day of a tricyclic (amitriptyline, nortriptyline, doxepin) as the point at which clinical failure can be assessed?
  - a) 100

d) 250

b) 150

e) 300

- c) 200
- 5. The use of which of the following agents has enhanced the therapeutic action of the tricyclics?
  - a) T4 b) T3

- e) Cylert
- c) Haldol
- d) Librium

# **Instructions for Self Evaluation Quiz**

Since many states now have mandatory continuing education requirements for pharmacists and it is anticipated that Maryland will soon pass a similar law, the MPhA is providing this special quiz for members so that they may receive the most benefit from continuing education articles appearing in the MARYLAND PHARMACIST.

The MPhA staff will grade and record this and any future quizzes and keep them in a personal file for each pharmacist. A grade of 90% or above is required in order to receive a passing mark. If you fail the quiz, it will be returned to you and you may resubmit the quiz only once with corrections made in a different color ink than was used the first time.

The MPhA will correspond with any state where a member is registered that requires continuing education participation to verify that member's participation in this program.

When submitting quizzes, please observe the following:

1) Paste your current mailing label to the quiz before sending it

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Mail to: MPhA, 650 W, Lombard St. Baltimore, Md. 21201

- 6. Which side effect of the tricyclics is also a sign of endogenous depression?
  - a) hypotension
- d) gas
- b) constination
- e) dry mouth
- c) hypertension
- 7. This tricyclic has been suggested as the drug of choice for treating the depressed cardiac patient.
  - a) doxepin
- d) protriptyline
- b) amitriptyline
- e) desipramine
- c) imipramine
- 8. Untreated depressive episodes are self-limiting and usually last for an average of six months to one year.

True or False?

- 9. Select the estimated adult lethal dose for tricyclics.
  - a) 1000 mg
- d) 4000 mg
- b) 2000 mg
- e) 5000 mg
- c) 3000 mg
- 10. Which of the following is not a symptom of tricyclic abrupt withdrawal?
  - a) insomnia
- d) irritability
- b) nausea
- e) diarrhea
- c) vomiting
- to the MPhA office. Use the boxed-in space provided on the quiz front. Please use the label from this copy of the MARY-LAND PHARMACIST only. This will serve as a membership
- 2) Use business-size envelopes when mailing to the office.
- 3) Please submit this quiz and others as soon as possible after receipt.
- 4) Please use appropriate amount of postage.
- 5) Correct Quiz answers are available upon request from the MPhA office; call or send a self-addressed, stamped envelone with the quiz.
- 6) Remember this is a free service for members of the MPhA only.

The MPhA will keep records for each participant and will issue a certificate annually showing the number of quizzes which have been successfully completed. Watch for other continuing education articles and quizzes in future issues of the MARYLAND PHARMACIST.

# When is a side effect a sign of effectiveness

With Brethine, it is when the highly effective action of the drug affects skeletal muscle as well as bronchial smooth muscle, causing tremor in some patients.

It is important for you, the pharmacist, to realize that Brethine is a  $\beta_2$ adrenergic agonist. The result of this action will be highly effective bronchodilation ( $\beta_2$  receptors in bronchial smooth muscle) and, sometimes, tremor (β<sub>2</sub> receptors in skeletal muscle of particularly sensitive patients).

If you are asked about tremor, you should be aware that tremo usually temporary, that it is a sig that Brethine is working and that easier breathing will continue ev after the tremor subsides (usuall in a week or two).

Patients should follow a bedtime morning, and midafternoon dosage schedule to avoid overlapping dosage. They should minimize their intake of coffee and other caffeinated beverages and see their physician.



Information, a summary of which follows:
Tablets contain 5 mg. (equivalent to 4.1 mg. of free base) of Brethine, brand of terbutaline sulfate.
Indications: As a bronchodilator for bronchial asthma and for reversible bronchospasm which may occur in association with bronchitis and emphysema.
Contraindications: Known hypersensitivity to sympathomimetic amines:
Warnings: Usage in Pregnancy: The safety of the use of Brethine, brand of terbutaline sulfate, in human

pregnancy has not been established. The use of the drug in pregnancy, lactation, or women of childbearing potential requires that the expected therapeutic benefit of the drug be weighed against its possible hazards to the mother or child.

Usage in Pediatrics, Brethine, brand of terbutaline suifate, tablets are not presently recommended for children below the age of twelve years due to insufficient clinical data in this pediatric group.

Precautions: Brethine, brand of terbutaline sulfate, should be used with caution in patients with diabetes, hypertension, and hyperthyrioidism. As with other sympathominetic bronchodilator agents.

Brethine, brand of terbutaline sulfate, should be

administered cautiously to cardiac patients, especi-those with associated arrhythmias. Although the co-comitant use of Brethine, brand of terbutaline suits with other sympathomimetic agents is not recom-mended, the use of an aerosol bronchodilator of the adrenergic stimulant type for the relief of an acute bronchospasm is not precluded in patients receivil chronic oral Brethine, brand of terbutaline sulfate therapy.

therapy.

Adverse Reactions: Commonly observed side effects include nervousness and tremor. Other reported reactions include headache, increased hear rale, palpitations, drowsiness, nausea, vomiting, an sweating. These reactions are generally transient in



# Maryland SAPhA News



Newly elected SAPhA officers are: Peter J. Manso, Vice President; Lisa L. Gillespie, Secretary; and Ruth Sammel Blatt, President.

The Student APhA of the University of Maryland has been rather busy in the past few months. The action started with the election of new officers. After a tough race, the outcome was: President — Ruth Sammel Blatt; Vice President — Pete Manso; Secretary — Lisa Gillespie. Richard Mills was appointed program director.

On April 19th, SAPhA sponsored a debate on the very popular topic of Laetrile. Robert Henderson, R.Ph. presented the pro argument and Peter Howard Rheinstein, M.D. presented the cons. Following a half hour talk by each, there were questions posed by a reactor panel consisting of three SAPhA members. Linda Oderda, Doug Haggerty and Russell LeSage did an excellent job responding to the issues presented by the two men. Questions were then taken from the audience.

At two of our recent luncheon meetings we had speakers who drew a large crowd. On April 13th, Mel Rubin spoke to us about job opportunities and what the "real world" is really like. On May 4th, Vincent DePaul Burkhart, director of Pharmacy Services at the University of Maryland Hospital, spoke about the pharmacy at the University of Maryland Hospital, positions available and residency programs.

So, as you can see, SAPhA has been quite busy and we hope to have an even better year next year.

Pictures courtesy Paramount Photo Service



A large SAPhA turnout heard Melvin Rubin discuss employment opportunities in Retail pharmacy.

# Drug Product Problem Report\*

#### KCI - OOPS!

A mislabeling of a potassium chloride oral solution with regard to its content (the label stated 0.5 mg/5 ml whereas it actually contained 0.5 g/5 ml) was spotted by a pharmacist and a pharmacy technician in California. Apparently both the manufacturer and the distributor had failed to check the labels for the content statement before distribution. The distributor recalled the mislabeled lot.

## Rubber Rubbed off

A report of particulate matter floating in the solution after two vials of anti-cancer drug had been reconstituted was submitted by a pharmacist at a medical center in Pennsylvania. The manufacturer examined the vials, and confirmed the presence of particulate matter which was identified as rubber coming from abrasion of the vial closures. The firm added that it had recently improved its quality control procedures to minimize the occurrence of such particulate matter.

# Cracked Tablets Subpotent

"Coated tablets cracking open in the middle, indicating poor coating or gas buildup within tablet" was the comment received from a community pharmacist in Florida about one lot of propantheline bromide tablets. An FDA follow-up inspection for the report revealed the firm's tests of this lot and three others showed them all to be subpotent. The firm initiated a recall to all its primary accounts.

# I.M. Pyrogen

"This lot possibly contains a pyrogenic agent" was the conclusion of a hospital pharmacist in Texas after he had observed fever and numbness of limbs in a number of patients who had received intramuscular injections of a multiple-vitamin preparation. This was the only DPPR report received on this lot; but follow-up testing was, nevertheless, initiated by both FDA and the manufacturer and showed the lot to be pyrogenic. The firm recalled the lot involved.

#### Tablet Hardness Corrected

"Tablets are cracked, chipped" was the comment received from a New Jersey hospital pharmacist regarding one lot of neomycin sulfate tablets. On checking its retained samples of the lot, the manufacturer discovered that the tablets were at the lower range of its internal specifications for hardness. The firm responded that the appropriate correction would be made.

# Non-conforming Dropper and Label

A pharmacist in Texas noted that the label of a ferrous sulfate solution listed the dosage as 0.4 ml and 0.8 ml for children under and over 4 years of age, respectively, while the dropper enclosed with the bottle was calibrated at 0.5 ml and 1 ml. This, he believed, could be confusing to the public. The company responded that it had revised its labeling to conform with the calibrations on the dropper.

# Punchless I.V. Spike

Wastage of a costly fibrinogen injection because of instances of the stopper's being pushed into the vial upon insertion of the I.V. set was reported by a hospital pharmacist in Pennsylvania. An FDA inspection at the manufacturer revealed that the cause had been traced to the I.V. spike. As a result, the spike is now being made in a different mold and the composition of the spike has been changed.

# Oil + Liner - Sinking Residue

The incompatibility of a cap liner system with oil of cloves was discovered by the manufacturer following a report by a North Carolina community pharmacist. The pharmacist had reported a white residue at the bottom of a bottle of the product. It did not dissolve with shaking. The firm recalled the lot mentioned in the pharmacist's report, plus one other.

# **Fading Tablets**

A community pharmacist in Iowa reported the fading of the blue color in some tablets of a combination antihistamine-decongestant preparation. He indicated that this happened only when the manufacturer failed to package the tablets in opaque bottles. Following his report, the manufacturer began packaging the product exclusively in opaque containers.

<sup>\*</sup>This report covers some of the recalls, product improvements, and explanations to which the Drug Product Problem Reporting Program has contributed. The product and company names are omitted; and no reflection on any specific manufacturer, distributor, reporter, or product is intended or should be inferred from the case studies. It is hoped that these examples will indicate to the reader some of the problem areas where he or she may want to be alert; e.g.: package insert information, package designs, labeling, unusual or improper drug product appearance.

#### Perforated Potency

"Professional observation and reporting from the pharmacist is an invaluable adjunct to our control system" was the commendation received from a manufacturer in response to a report from a hospital pharmacist in Maryland. The pharmacist had reported that the labeling of the potency on the foil wrapping of some acetaminophen suppositories was printed across the perforated section so that when the suppositories were separated the strength could not be read. The manufacturer took steps to correct the problem within the production line and alerted its quality assurance inspectors.

#### Weight Variations Obvious

A follow-up investigation by FDA on a pharmacist's report of the existence of wide variations in the sizes of the tablets of a prenatal product determined that the reported lot and one other lot were involved. Both lots were recalled.

# A Lot Missing

"Lot number and expiration date missing from label" was the comment received from a community pharmacist in Delaware. Following his report, the manufacturer reviewed its production procedures and modified them so that products without lot numbers could be detected on the production line.

#### Particulate Matter Present

Black particles in two separate lots of a buffered saline solution were reported by hospital pharmacists in Washington and Texas. A follow-up inspection by the Food and Drug Administration at the firm's premises noted particulate matter in these two lots plus one other. The presence of particulate matter was confirmed by the manufacturer's stability studies. This eventually led to the recall at the wholesale level of several lots of this and other related products by the manufacturer.

# Subpotent Nitrofurazone

Pharmacists at a Pennsylvania hospital reported that one lot of a nitrofurazone solution was darker than normal and another lot contained particulate matter. Subsequent analysis by the firm revealed the product to be low in potency for reasons not yet identified. All lots of the product involved were recalled.

# Spinal Anesthesia Tray Label at Variance with Vial Label Inside

Incorrect labeling of the percentage strength of the lidocaine contained in a spinal anesthesia tray was reported by a Michigan hospital pharmacist. The strength on the outside package read 10%, whereas the vial actually contained in the tray was labeled correctly as 1%. The firm recalled the two lots involved.

# Color Change Made on Label

Modifications in the colors used to label its dextrose injection and lidocaine injection will be made by one manufacturer following a Drug Product Problem Report from a hospital pharmacist in Maryland. The pharmacist had expressed concern because the labels of the two products were very similar and had nearly caused an accident. Although politely pointing out that labels are intended to be read, not absorbed colorimetrically, the manufacturer is changing the colors on the label of one of the products in an attempt to differentiate them further.

# Rusty Urea

Rust-type contamination in two lots of urea crystals was confirmed by the manufacturer following a California hospital pharmacist's report of black particles and foreign material in solutions made from one of the lots. The firm recalled the two lots involved.

# Additional Inserts Added

"While the package insert says that unused partial vials may be stored at 4° C for up to 72 hours, this information does NOT appear on the vial itself, thus encouraging hospital personnel, who do not have the package insert (one insert is issued for 12 vials), to throw away the remainder of this expensive drug" was the report received from a hospital pharmacist in Hawaii about an injectable antineoplastic agent. In response to his report, the manufacturer will start enclosing twelve package inserts in each box of twelve vials.





June 16-18 — MSHP Seminar, Williamsburg

June 18-22 — MPhA Convention, Ocean City — Fun in the Sun at the Carousel

Sept. 10 — MPhA Dinner Theatre

Sept. 17-21 — NARD Convention, New Orleans

Oct. 29 (Sun.) — Alumni Association Oyster Roast

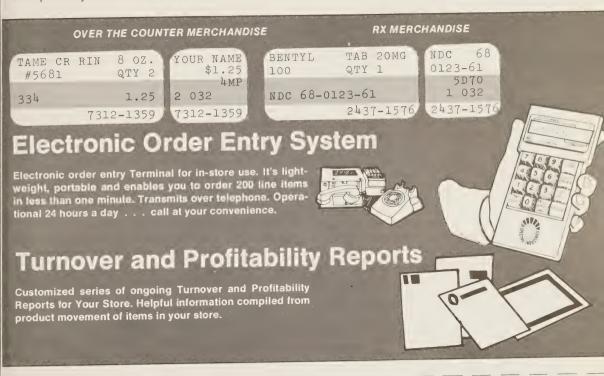
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# Report from the Board of Pharmacy

by
— Paul Freiman
Secretary

The Commissioners of the Maryland Board of Pharmacy met at 10:00 a.m. in the O'Conor Building, 201 West Preston Street, Baltimore, Maryland. Present were President Ralph T. Quarles, Mr. Robert Snyder, Mr. Charles Tregoe, Mr. Paul Freiman, and Mrs. Estelle Cohen. Also present were Mr. Irv Meyers, Mr. Nathan Gruz and Mrs. Ethel Stern.

Mr. Quarles asked at the beginning of the meeting for a commissioner to take over the vacant position of Secretary of the Board. Mr. Freiman agreed to accept the position on a trial basis, in order to assess his ability and time in the position.

The minutes from the March 15th meeting were corrected to indicate that Mr. Freiman did not inform Mr. Levitt that he was in violation of Maryland Pharmacy Law, but, in fact, informed the Board that he believed the issuance of a pharmacy license to Mr. Levitt's establishment, was in violation of the law.

A letter from Kaufmann's Pharmacy was read, indicating that he was prepared to fill all prescriptions presented to him, including Narcotics prescriptions. On motion by Mr. Freiman, seconded by Mr. Tregoe, it was decided that this pharmacy was in compliance with the law, and that a letter to this effect will be sent to David C. Clarke.

A letter from Arcade Pharmacy concerning the need for a new safety container on prescription refills was read. Federal Law does require this, and it was decided to inform Mr. Karl G. Wagner of this fact.

The Board was informed by Mr. Freiman that Rite-Aid had agreed to have two of their supervisors available to fill emergency prescriptions after pharmacy hours. The prescription must be phoned into the supervisor by a physician, and the police must meet him at the pharmacy. This was agreed to by the Medical Society, and the information will be published in their journal.

A complaint was received that St. Paul Pharmacy was being opened at 7:30 a.m. without a pharmacist. The pharmacist indicated that the pharmacy section was secured until the pharmacist arrives. A request was made to Mr. Meyers to have an inspection done at 7:30 at St. Paul, to insure that they are in compliance with the law.

The request from the Maryland Psychiatric Research Center for a pharmacy permit for its outpatient psychiatric clinic on the grounds of Spring Grove Hospital was denied by the board. A letter to this effect will be mailed to William T. Carpenter, Jr., Director. A memorandum from Mr. Jack C. Tranter, indicated that what was proposed did not meet the requirements for a hospital pharmacy under Maryland Law.

The complaint from board members about the failure of correspondence to be taken care of within a reasonable time was noted. Mr. Freiman stated as board secretary he will be in the office at least once a week, and hopefully can have Board mail handled in a more expeditious manner. Mrs. Cohen mentioned a consumer complaint that took three weeks to answer, and resulted in an embarrassment to her, and a feeling on the part of the consumer that the board was indifferent to his complaint. It is hoped that in the future this problem will be overcome.

The recent legislative session was discussed. HB 227 which increases disciplinary power of the board was passed. HB 197 to allow the Board to set fees, and HB 1904 and SB 1071 concerning mandatory continuing education were defeated. HB 1477 to add one or more consumers to all boards was discussed. The board agreed to ask the governor for a veto hearing since the bill is poorly written, and since the medical and nursing boards were exempted from having a consumer member.

Ethel Stern said that we will soon be getting an administrative assistant that we will share with the Dental Board. She expressed the hope that this will help relieve some of the problems our board has been having. It was also announced that the Board has received \$1155.00 for expenses to the NABP convention in New Orleans. A letter to Mr. Leonard Albert, thanking him for his assistance, will be sent.

The meeting date for the next meeting of the Board of Pharmacy has been set for Wednesday, May 24th, 1978, since the 3rd Wednesday is in conflict with the APhA convention. At this meeting both Mr. Levitt and Mr. Henderson will appear with their lawyers, to answer the Board's belief that their pharmacy licenses were issued in error and should be revoked.

The Board adjourned at 2:00 p.m.

Respectfully Submitted,

Paul Freiman, Secretary Maryland Board of Pharmacy

# **Spring Regional Focuses** on Reports and Resolutions





John Mitchell, Assistant Executive Director of the APhA, presented the luncheon speech on the Drug Regulation Reform Act of 1978. Maryland Pharmacists were the first to be urged to contact their Congressmen on the objectionable portions of this historic bill.

The April 20th meeting at the Quality Inn in Towson heard a report from George Stevenson, Chairman of the MPhA Industry Relations Committee. George indicates he will retire as Chairman from this most active Committee following the MPhA Convention.

Pictures courtesy Paramount Photo Service



Several Members of the Ladies Auxiliary of the Maryland Pharmaceutical Association (LAMPA) took the opportunity of the Spring Regional Meeting to discuss plans for LAMPA's twenty-fifth anniversary to be held in conjunction with the MPhA Convention.



The business meeting of the House of Delegates was observed by (left to right) Sam Lichter, speaker; Richard Parker, MPhA President; and David Banta, Secretary.

# Pharmacy Times Article Seeks Member Help

In the U.S. Capitol, Navy technicians are dispensing prescriptions to members of Congress and their families — without the direct, day-to-day personal supervision of a pharmacist, according to an article in the May 1978 issue of Pharmacy Times.

In this connection, *Pharmacy Times*' editor Irv Rubin warns: "These Navy technicians, in effect, have *totally* replaced pharmacists. This is in direct conflict with the proper use of technicians who are intended to serve as pharmacist-extenders — *not* as pharmacist-replacers. Any pharmacist who has ever worked with technicians is well aware of their limitations with respect to pharmaceutical knowledge."

This is not to say that there is no place for technicians in pharmaceutical services. However, it is to say — and to emphasize — that technicians must be closely supervised by pharmacists. Whatever technicians do — such as typing Rx labels — must be double-checked by a pharmacist who bears the ultimate responsibility for dispensing prescriptions. To permit technicians to dispense today's potent Rx drugs on their own — on a daily basis — is against the patient's best interest.

It also is understandable that the military services need technicians to safeguard against shortages of trained manpower in preparing for their wartime missions of combat. However, no military emergencies exist in the U.S. Capitol.

#### Congress Has Recognized Clinical Pharmacy

Interestingly, members of Congress — the patients of the U.S. Capitol pharmacy — have themselves recognized the importance of pharmacists by passing the Veterans Health Care Amendments of 1977. This Congressional legislation notes the significance of Clinical Pharmacy — as provided by pharmacists. Specifically, the U.S. Senate and the House of Representatives asserted: "Where clinical pharmacy services of this scope have been utilized, studies indicate that medication error rates have decreased substantially, that inappropriate drug utilization has been reduced, that adverse drug reactions have been averted, and that substantial dollar savings have been realized."

#### Contact Your U.S. Congressmen — Now!

What can people connected with Pharmacy do to improve a pharmaceutical situation that does *not* serve the *best* interests of the public?

The answer: Flood members of Congress with "gallons" of messages urging them to insist that a full-time pharmacist be assigned to dispense and/or personally supervise the dispensing of prescriptions in the U.S. Capitol pharmacy. Also, pharmacists can urge their relatives, friends, customers, local newspaper editors, civic groups — and anyone else — to write their U.S. Con-

# EDI Supplement Now Available from APhA

A new 128-page Supplement to the internationally acclaimed reference source Evaluations of Drug Interactions has just been published by the American Pharmaceutical Association, the national professional society of pharmacists.

This new Supplement, prepared under the same rigorous review standards as the main volume of EDI, includes 36 additional drug interaction monographs, covering several hundred drug interactions not previously evaluated in EDI.

In addition, the new Supplement introduces a new element: the Abbreviated Monograph. The 31 abbreviated monographs are included in the new Supplement to assess their effectiveness in providing guidance to practitioners on interactions about which there are only meager reports in the literature.

The comprehensive index utilized in EDI is the key to its growing acceptance as a practical, usable reference source. Any interaction discussed in EDI can be located easily by looking under either interacting drug. Trade names are also included in the index with cross-reference to their appropriate nonproprietary names.

EDI is the ideal tool for detecting, managing, and understanding drug interactions. The main volume together with the newly prepared Supplement cover several thousand potential drug interactions.

In addition to providing detailed information on mechanisms and effects, EDI gives specific practical recommendations concerning alternative therapy, necessary laboratory tests, and dosage adjustments.

Evaluations of Drug Interactions provides valuable, usable information generated by a multidisciplinary group of more than 200 experts and is designed for use by all health-care professionals.

The new Supplement to Evaluations of Drug Interactions can be obtained from: Order Desk, American Pharmaceutical Association, 2215 Constitution Avenue, N.W., Washington, DC 20037. The 128-page, 15 x 23 cm., softbound book is \$7.00 (APhA Members, \$4.00). The EDI Main Volume and Supplement can be obtained for \$20.00 (\$13.00 for APhA Members). Orders totaling less than \$50 must be prepaid or accompanied by a purchase order. Foreign orders must be prepaid. APhA members should include a mailing label from American Pharmacy or APhA Weekly to establish member identification.

gressmen. These letters, wires, postcards, etc., should be addressed as follows:

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## Phi Delta Chi Award Presented



At the recent annual Phi Delta Chi (lota Chapter) banquet Dr. Gary Lesher was presented with the first Hubert H. Humphrey Award. An award presented to the person displaying outstanding rapport with the students outside of the classroom. Dr. Lesher is an Assistant Professor of Pharmacology and Toxicology at the U. of Md., School of Pharmacy. Seated: Dr. Lesher's wife, Lynn; Jefferson Gregory, Vice President of lota Chapter; and Dr. Lesher.

# **Steve Cohen Receives Grant**

In recognition of outstanding, original research in hospital pharmacy, the Roche Hospital Pharmacy Advisory Board has recently announced the winners of the 1977 Roche Laboratories Hospital Pharmacy Research Grant Program. Each year, ten research grants of \$1,500 are awarded on a competitive basis to practicing hospital pharmacists for original basic research in their field.

Established in the interest of continued excellence in hospital pharmacy, the research grants are awarded for projects in any phase of hospital pharmacy. Proposed topics may deal with practical operation, drug communication services, continuing education, or research developments. The projects are submitted for review and final selection to the Roche Hospital Pharmacy Advisory Board, composed of ten practicing hospital pharmacists.



(Left to right) Jim Hunter — Roche Division, Sales Manager, F. W. Morrison — Roche Sales Representative, Steven Cohen, The Good Samaritan Hospital, Baltimore, Maryland.

### **Alumni Association Nominating** Committee Report

The nominating committee wishes to express its appreciation to President William Weiner for the opportunity to serve the Alumni Association, and would, also, like to express sincere thanks to all the officers for their commitment to the Association during the past year.

The slate of nominees is as follows:

OFFICERS For Honorary President ... Milton L. Elsberg For President .......George C. Voxakis For First Vice President, Bernard F. Macek For Second Vice President Sanford L. Posenbloom

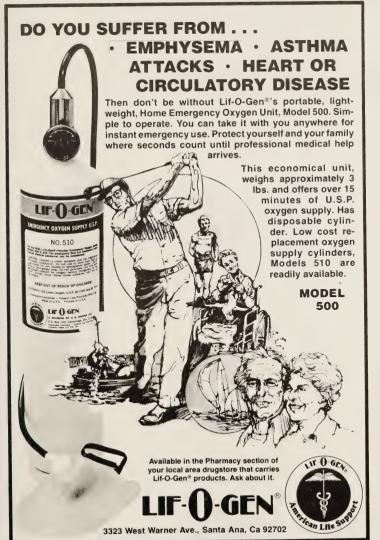
For Secretary......Joseph W. Loetell, Jr. For Treasurer ......Ronald A. Sanford For Treasurer Emeritus .H. Nelson Warfield

> Respectfully. Nominating Committee

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# Remember, the summer of '77?

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We hope we answered their questions. Certainly, we took their suggestions to heart.

And when the 10 weeks were over, we parted knowing that we'll enjoy seeing each other in the years ahead.

And reminiscing about the summer of '77.



P1978, The Upjohn Company, Kalamazoo, Michigan

# **New Drugs Introduced in 1978**

A new prescription drug to fight pulmonary blood clots, one for advanced breast cancer and another to aid in the control of certain types of epilepsy were introduced in the U.S. in the first quarter of 1978. A "do-it-yourself" home pregnancy detection kit and a treatment for secreting skin lesions were among other medical products recently introduced. Following is a description of each.

'Abbokinase' (urokinase): researched, developed and manufactured by Abbott Laboratories, North Chicago, IL, was approved by the Food and Drug Administration (FDA) in January. This blood-clot dissolving agent treats massive pulmonary embolisms (blood clots in the lungs) by activating a patient's own system for breaking up fibrin, the protein that is the essential part of a blood clot.

Pulmonary blood clots cause an estimated 200,000 deaths each year in this country, third only to heart disease and cancer. Urokinase had been marketed in Japan and several European nations before receiving U.S. approval. To make it readily available throughout the U.S., Abbokinase is initially being distributed from North Chicago and 45 strategically located hospitals. Because of its profound effect on the clotting mechanism, special precautions, including laboratory monitoring, must be taken to prevent complications. The drug is recommended for use only by physicians with wide experience in the management of thrombolic disease and in hospitals where the recommended clinical and laboratory monitoring can be performed.

'Nolvadex' (tamoxifen citrate): researched in the United States by the Stuart Pharmaceuticals Division of ICI Americas, Inc., Wilmington, DE, was approved by FDA in late December and introduced in January. The drug was discovered by Imperial Chemical Industries Limited and introduced in the United Kingdom in 1973. Intended for the palliative treatment of advanced breast cancer in postmenopausal women, it is a nonsteroidal antiestrogen. Breast cancer is the leading cause of cancer deaths in American women; 90,000 new cases are detected each year, and an estimated 33,000 deaths result annually.

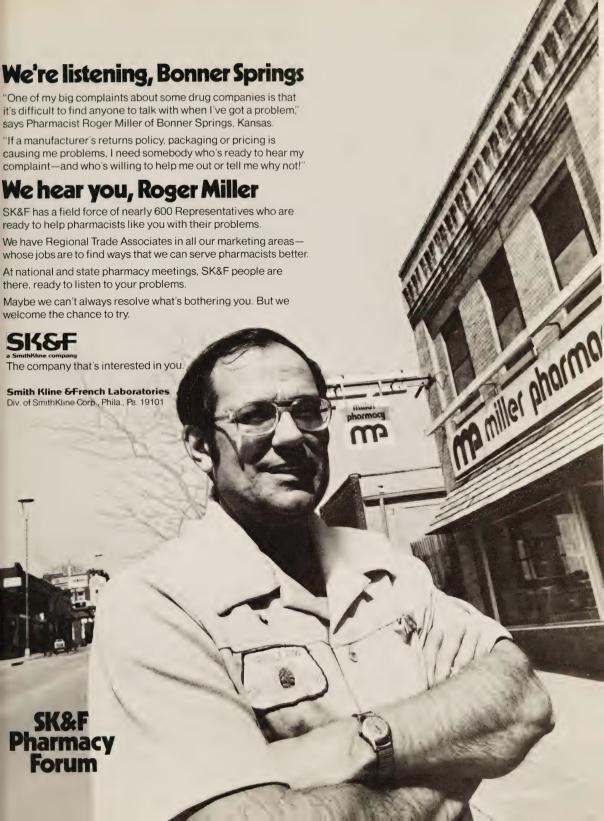
Nolvadex works by inhibiting estrogen from binding within those breast cancer cells which contain estrogen receptors, thereby inhibiting cell division. The most frequently reported side effects were generally of a minimal non-life-threatening nature. Nolvadex is marketed in more than 15 other countries.

**'Depakene'** (valproic acid): developed and manufactured by Abbott Laboratories, North Chicago, IL, was approved by FDA in February. It is indicated for use as sole or adjunctive therapy in treatment of simple and complex absence epileptic seizures, including petit mal, and as adjunctive therapy in patients with multiple seizure types which include absence seizures. The product has been marketed for up to 10 years in various European countries as sodium valproate.

Abbott signed an agreement with Labaz of France in December, 1974, and initiated clinical investigations to bring the drug to the U.S. market. At the request of FDA, the company moved with dispatch to compile all data and submit a new drug application in September of 1977. The FDA's Neurologic Drugs Advisory Committee recommended approval in October. After review of additional data and another study submitted on January 30, 1978, the agency approved the new drug application less than 30 days later.

**'E.P.T.'** (early pregnancy test): offered by Warner/Chilcott division of Warner-Lambert Company, Morris Plains, NJ, was nationally introduced in January. Simple to use and read and highly accurate, the In-Home Early Pregnancy Test (called E.P.T.) allows a woman to perform her own pregnancy test at home. E.P.T. can detect a pregnancy as early as nine days after a missed menstrual period. The test senses the presence of Human Chorionic Gonadotropin (HCG), a hormone which occurs in the urine during pregnancy. The kit simply verifies wherher or not the hormone is present in adequate quantity. E.P.T. is available in pharmacies, without prescription.

'Debrisan' (dextranomer): researched and developed by Pharmacia Laboratories, Piscataway, NJ, was first marketed in the U.S. in November. It cleanses secreting skin lesions such as leg ulcers, bedsores and other serious surface wounds. Over one million persons need medical treatment for these types of skin ulcers annually. Debrisan works by drawing unwanted fluids, bacteria and other contaminants away from the wound's surface. A derivative of dextran, Debrisan is in the form of tiny, absorbent beads, 0.1 to 0.3 mm in diameter. Debrisan was first introduced in Sweden in 1974.



# New Blood Storage Technique Developed in Maryland

Recent concern about the quality of transfused blood has led Denise Harmening, a University of Maryland instructor, to research an entirely new concept in blood preservation. An instructor in the Medical Technology Program at the School of Medicine, Ms. Harmening has devised a unique system for preserving blood, utilizing solid ion exchange resins to replace traditional chemical agents. Laboratory tests indicate that her system not only lengthens the storage time of blood, but also may increase the quality of stored blood. Ms. Harmening's work is expected to have a major impact on the availability of blood for immediate use in trauma and surgical cases, and may have potential for fulfilling increased blood demands in times of disaster or national defense.

The new resin system may have several practical applications. According to Ms. Harmening, recent studies have shown increased mortality associated with transfusing blood low in the organic phosphate 2,3, DPG in patients with anemia, hypertension, cardiac shock, acute blood loss, and hypoxia. Other studies have shown improved heart function following transfusion of blood high in this organic phosphate. In tests using the resins, high levels of 2,3 DPG and adequate levels of atp, a second essential phosphate, were maintained throughout the 28 day storage period.

Ms. Jane Kuchta, supervisor of the University of Maryland Hospital Blood Bank, explains that in most storage systems now utilized, the level of 2,3, DPG declines rapidly after seven days of storage. Therefore, blood less than seven days old should be used for some pediatric, cardiac, surgical, and trauma patients. Ms. Harmening's system yields a 2,3 DPG blood level on day 21 that is often higher than the day drawn. To date, no

other researcher has been able to maintain high levels of both organic phosphates, 2,3 DPG and ATP, without the use of several chemicals in the blood bag. Use of the solid resins results in a product that contains no other chemical than the licensed anticoagulant. The resins are easily filtered out of the blood during the transfusion.

Denise Harmening is the first to apply the use of this ion exchange resin to blood preservation, although variations of the resin are commonly used in water purification, wine distillation and pharmaceutical concentrating methods. She began her research in 1974 to determine the effectiveness of solid buffers in blood preservation. The resin system has been accepted for patenting by Research Corporation, an international, non-profit organization which promotes advances in science and technology originating in universities. The anticipated patent issuing date is July, 1978. While the organization reviews over 500 applications each year only 35 to 50 inventions are accepted for patent disclosure.

Also in July, Ms. Harmening is scheduled to present a paper on her work in Paris, France at the Joint Congress of the International Society of Hematology and the International Society of Blood Transfusion. She presented an abstract on the use of her ion exchange resins as a blood preservative system at the November, 1977 annual meeting of the American Association of Blood Banks held in Atlanta, Georgia.

A registered medical technologist, Ms. Harmening received her master's degree from the University of Maryland School of Medicine in August, 1976. She is currently pursuing her doctorate degree in clinical pathology at Maryland while further developing this research.

Pictures courtesy Paramount Photo Service



On April 13, 1978, the MSHP and MPhA held a joint meeting. A good crowd turned out for the cocktails and buffet at the Kelly Memorial Building.



Pharmacists then moved across the street to Howard Hall to hear Edward J. Kowalewski, Professor and Chairman of Family Medicine at the University of Maryland School of Medicine to discuss "The Pharmacist and the Family Practitioner."

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### LETTERS



Mr. David A. Banta Executive Director Maryland Pharmaceutical Association 650 W. Lombard Street Baltimore, Md. 21201

Dear Mr. Banta:

Kappa Psi Pharmaceutical Fraternity is preparing to celebrate its Centennial Anniversary in Scottsdale, Arizona in 1979. We would sincerely appreciate it if you would publish this letter in your journal. Our fraternity, which is the largest pharmaceutical fraternity in the United States and the third largest pharmacy organization in the United States, with a membership in excess of 45,000, is preparing to celebrate its 100th anniversary.

During the years, we have lost contact with many of our membership and we would like to reunite with our lost brothers in order to inform them of our Centennial celebration.

To all members of Kappa Psi who are presently not receiving the current issue of The Mask, our official publication, we encourage you to fill out the form below and return to our Central Office as soon as possible so we can inform you of the plans of our memorable event, and also update you on the present status of your fraternity.

Thank you for your time and consideration.

Sincerely yours,

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JULY, 1978 VOL. 54 NO. 7



# **MPhA Convention Reports**

# **Drug Use in the Elderly**

- David A. Knapp, Ph.D.

# P & T Committee report on Desipramine Hydrochloride

- Thomas C. Majerus, Pharm.D.

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Schaf Doal

#### President's Report Annual Convention — June 1978

During the past year, the Maryland Paarmaceutical Association has been involved in a period of analysis and re-examination of its goals and priorities. The Association has experienced change and has adjusted to these changes without sacrifice in striving for the objectives of the Association.

The change in Executive Directors required a great deal of cooperation on the part of the membership and staff.

In giving of his time during the interim between Directors, Milton Friedman proved to be a continuing asset to our Association. Of course, he was not alone in this period of transition and I would like to thank Henry Seidman, Mel Rubin, Don Fedder and others who gave of their time and talents.

The first order of concern in the new year was attaining financial stability. Our finance chairman, Stanley Yaffe, together with a fund-raising committee consisting of Abe Bloom, Al Posner, Gary McNamara, Al Turner, Charlie Spigelmire, and others were instrumental in promoting a dinner-theatre party at Colony 7 which produced over \$2,000 to help cover expenses of the Association. This effort relieved the immediate crunch and our new director-editor of the Maryland Pharmacist helped with the long range problem by bringing the journal up to date and obtaining greater revenues in its publication. Other financial necessities included a dues increase and use of reserve funds. We now are in a stronger position due to the recovery of nearly \$5,000 of funds nearly lost in the aborted Mexico trip in which deposits were made with Hyatt Regency International. Through the efforts of Dave Banta and with the assistance of Ron Lubman, American Pharmaceutical Association and myself, we have regained the use of these funds through participation at the APhA Convention. The Treasurer's report will show our current status.

Your president, along with Dave Banta, attended several political functions in the past year. During a Chamber of Commerce function at Annapolis, we spent some time with Acting Governor Blair Lee III and had opportunity to discuss several issues and plans for Pharmacy. We also have had the privilege of meeting many

incumbent legislators and potential candidates for elective office. During the year, we visited the Medicaid offices and took a guided tour of its facilities. We also met with the officials of the Division of Drug Control and greeted the new Director of the Medical Assistance Policy Administration, Charles Putnam. We attended Medical Assistance Liaison Committee meetings, met with the officers of HEW Region III where we presented testimony concerning reimbursement procedures for vendors with recommendations for usual and customary in the National Health Insurance which is in our future. I attended the NARD Convention and Legislative conference as well as the APhA Convention.

Dave and I have attended most of the meetings of associate organizations within the profession, including installation programs, annual meetings, and fungatherings at Prince Georges-Montgomery Pharmaceutical Association, Baltimore Pharmaceutical Association, Anne Arundel Pharmaceutical Association, Eastern Shore Pharmaceutical Society and Upper Bay Pharmaceutical Association and the University of Maryland Alumni Association. We have also participated in joint meetings with the Maryland Society of Hospital Pharmacists and the Baltimore Metropolitan Pharmaceutical Association. I would like to thank the leaders of these organizations for inviting us as their guests on several occasions. Art Riley has been a particular promoter of cooperation between our associations and I appreciate the assistance he and MSHP have rendered in programs affecting the profession.

At last year's convention we were made aware of a potential problem in the Baltimore area. Rite-Aid had assumed ownership of Read's stores and the hiring practices of the Company included polygraph testing procedures in the employee screening for security. With Edward Nussbaum, chairman of the Employee Relations committee, I went to the corporate headquarters of Rite Aid in Pennsylvania and met with Richard Kunkel, Executive in charge of employee relations. He informed us that he had no authority to change corporate policy or procedures, but he stated that no one was forced to take

(Continued on page 14)

# DRUG USE IN THE ELDERLY\*

David A. Knapp, Ph.D. University of Maryland School of Pharmacy

Although persons 65 years of age and older make up only about 10% of the population of the United States, they consume about 25% of all prescribed drugs used in the country. This paper will focus on drug use by the elderly in a medical context, and several potential problems will be presented and discussed. Illicit drug use will not be covered.

#### **Drug Utilization Information**

Common sense tells us to expect higher drug use in the elderly because of the increased morbidity in this age group. The three tables attached to this paper present information from the 1975 National Ambulatory Medical Care Survey and shed some light on the use of drugs. Table 1 shows that the elderly visit physicians two-thirds again as frequently as those under 65 years of age. Table 2 illustrates that, in addition to the higher frequency of visits, the seriousness of the problem leading to each visit is higher in the 65 years and older group. The duration of visits tends to be higher for the elderly, but even so, about 40% of the visits involve less than 10 minutes in face-to-face discussion with the physician. Finally, Table 3 indicates that almost two-thirds of all office visits by the elderly result in a drug being prescribed or an injection being administered. This rate of drug use, however, is not much less for the under 65 population.

In terms of dollars, an average prescription costs the elderly patients about \$5.50. Total drug expenditures per capita in 1975 were about \$120 for the elderly, about \$49 for all persons.

To this point we have been discussing prescriptions for out-patients. Within the hospital, drug use is even more frequent most hospitalized patients use multiple drugs during their stay with the average being about eight different drugs during a typical length of stay.

Information related to nonprescription drugs is harder to come by, especially if use by age categories is desired. It is estimated that Americans spent about four million dollars on nonprescription medications last year. It does appear however, that the elderly population uses fewer nonprescription medications than do younger persons. This may be because they rely more heavily on prescribed medications. There are certain exceptions to this, of course, since some types of self-medication drugs, notably laxatives, are used more frequently by older persons. We should not forget, however, the easy accessibility of nonprescription drugs in the home. When medicine cabinets were inventoried in about 300 homes in one community, an average of over 17 different non-prescription remedies was found.

#### Potential Drug-Related Problems

The high use of drugs among the elderly increases the possibility of the development of the variety of problems. These include:

1. Medical problems related to the high use of drugs *per se* regardless of age.

Since all drugs are basically foreign substances and involve not only the potential for benefit but the threat of harm, increased exposure means an automatic increase in risk. Such risk includes the possibility of adverse drug reactions associated with specific drugs, or interactions between drugs and food, drugs and laboratory tests, and drugs and other drugs being taken sumultaneously. Even presumably safe nonprescription drugs can sometimes even interfere with prescribed drug therapy. For example, certain antacids can interfere with the absorption of certain antibiotics.

2. The inherent risks associated with drug therapy is exacerbated in elderly patients.

Since persons age at different rates, there is more variability among patients with respect to physiology and, thus, the ability to handle drugs. Metabolism slows, there may be changes in the kidneys and in the liver, and the patient may suffer from multiple disease. Thus, elderly patients are by and large, harder to treat. It is more difficult to adjust drug therapy precisely to their needs.

3. The high use of drugs in the elderly can cause economic problems.

Office Visits by Persons Aged 65 and Over: National Ambulatory Medical Care Survey, United States, 1975<sup>1</sup>

<sup>3</sup>This report prepared by Raymond O. Gagnon, Division of Health Resources Utilization Statistics.

Table 1. Annual rate of visits to office-based physicians by age and sex of visitors
United States, 1975

	Age						
Sex	All ages	Under 15 years	15-24 years	25-44 years	45-64 years	65 years and over	Under 65 years of age
	N	umber of v	isits p	er 100	persons	per year	
Both sexes	273	189	222	275	343	426	255
MaleFemale	222 322	198 180	150 294	191 356	284 396	399 445	205 305

<sup>&</sup>lt;sup>1</sup>The bare populations used in computing the rates are national estimates published by the U.S. Sureau of the Census for the civilian noninstitutionalized population as of July 1, 1975, in Seizes PSS and PSC of Current Population Reports.

<sup>\*</sup>Presented at the Drug Action Coalition Workshiop on Drug and Alcohol Use among the Elderly, Rockville, Maryland, May 23, 1978.

Table 2 Number and percent distribution of office visits made by persons 65 years and over and percent distribution of office visits made by persons under 65 years by seriousness of the problem and disposition of the patient visit: bhited Scares, 1975

	Office visit				
Seriousness of the problem and disposition of the patient visit	65 years and over	65 years and over	Under 65 years		
	Number in thousands	umber in thousands Percent distribution			
All visits	93,061	100.0	1100.0		
Seriousness of problem  Not serious	32,560 33,111 27,389	35.0 35.6 29.4	51.5 31.7 16.8		
Disposition of visit <sup>2</sup> Return as specified time- Return if needed- No followup planned- Telephone followup planned- Amerited to hospital- Returned to referring physician-	65,198 17,827 5,615 2,836 2,753 2,510 1,018	70.1 19.2 6.0 3.1 3.0 2.7 1.1	57.1 22.9 14.5 3.8 2.8 2.0 0.9		
No face-to-face encounter with physician- 1-5 minutes- 6-10 minutes- 11-13 minutes- 31 minutes or more	1,291 11,083 25,078 28,495 22,545	1.4 11.9 27.0 30.6 24.2 4.9	1.2 17.0 32.1 26.0 17.5		

Based on an estimated 474,540,000 visits.
Percents will add to more than 100 because some patients required more than one

disposition.
Time spent in face-to-face encounter between physician and patient.

While drugs required during a hospital stay are paid for by Medicare, out-of-hospital drugs are not. Medicaid covers prescriptions, but most of the elderly are not poor enough to qualify, although high medical expenditures are often a very real burden. Private insurance seldom covers out-patient drugs. In addition to the lack of drug coverage, the elderly may also find it difficult to shop for the best price because of lack of mobility.

4. There are problems associated with using drugs properly.

Many patients, not only the elderly, do not understand the directions on prescription labels and complain that the labeling on nonprescription medications is unclear. For some drugs, adherence to a specified regimen is very important, such as in the case of hypertension therapy, while in others, such as treatment of symptoms, a rigid schedule is not so important. Patients need help in determining which drugs must be taken appropriately in order to avoid complications.

5. The effects of physical impairment in the elderly may interfere with drug therapy.

One example is failing eyesight. During a home visit, it was discovered that one elderly patient was keeping her variety of prescription medications in the refrigerator. Since her vision was too poor to read the labels of the drugs, she had poured the prescriptions into the egg compartments on the door and had labeled each in big letters with nail polish. While this solved the drug identification problem, the humidity in the refrigerator caused the medication to deteriorate.

Another example is the problem that patients with arthritis or poor coordination have in coping with the child-proof containers which are now required for both prescription and nonprescription drugs. It is important that the elderly realize that they can request the pharmacy to package these products without a child-proof cap. Finally, declining mental functions can lead to difficulties in patients on multiple drug therapy. If the patient is taking several drugs, each with a different dosage regimen, it is easy to become confused.

6. Finally, the whole gamut of social factors which affect all aspects of the elderly patient's life also affect drug therapy.

Living conditions, family ties, neighbors and friends, mobility, economic independence and a host of others, all affect the use of drugs.

#### Summary

Drug use in the elderly is much higher than in the under-65 population. This in itself is no cause for alarm. The elderly suffer more morbidity. Higher utilization, however, increases the exposure of this age group to a variety of problems associated with drugs. We should remember, of course, that not all the elderly suffer the problems discussed here. All, however, must be alert to the increased potential for drug-related problems and be prepared to help in a variety of ways.

Table 3. Number and percent of office visits made by persons 65 years and over and percent of office visits made by persons under 65 years by diagnostic and therapeutic services most frequently ordered or provided: thirted Scates, 1975 and therapeutic services most frequently ordered or provided: thirted Scates, 1975 and therapeutic services most frequently ordered or provided: thirted Scates, 1975 and therapeutic services are serviced or provided the services of the servic

•	Office visit				
Diagnostic and therapeutic services most frequently ordered or provided	65 years and over!	65 years and over	Under 65 years		
Diagnostic services	Number in thousands		Percent		
Limited history, exam. Blood pressure check Clinical lab test— General history, exam. X-ray. X-ray. Education of the control o	51, 44, 23, 11, 7, 6, 5,	112 48.2 24.9 139 11.9 107 7.5 55 6.6 120 6.0	50.6 30.2 22.5 16.5 7.3 2.8 4.4 1.0		
Therapeutic services  Injection- Medical counseling- Office surgery  Immunication, description  Temmination, description  Temmination, description  Tempination, description  Tempination		16.8 120 12.1 133 6.3	43.7 13.2 12.3 6.8 4.9 4.6 2.2		

Based on an estimated 93,061,000 visits.



# Meet our SAM.



# His name is Ken.

Ken Morrill is the Southeast Region Special Accounts Manager (SAM) for LEDERLE STANDARD PRODUCTS. He's our sales trainer...trouble shooter...liaison man...a special link between you and Lederle. His business is *service*...a commodity you don't see much of these days. A basic philosophy of LEDERLE STANDARD PRODUCTS.

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To serve you.

But if ever a problem...a question...a need...arises, your Lederle Representative will call in Ken Morrill, otherwise known as SAM.

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# Pharmacy Notification for Surveillance and Drug Utilization Review in a Tuberculosis Control Program

David Glasser, M.D., M.P.H.
Director,
Bureau of Disease Control
Baltimore City Health Department
111 North Calvert Street
Baltimore, Maryland 21202

The thrust of tuberculosis control in the United States has shifted from mass screening to containment through epidemiology, case-management, and isoniazid chemoprevention. This task has become increasingly difficult since tuberculosis has entered the "mainstream" of medicine, and health departments no longer directly supervise all cases.

A mechanism which identifies all cases in the community, allows monitoring of chemotherapy, and integrates the public and private sectors of medical care is therefore critical to avert disruption of effective treatment services and preserve disease control.

Since the 1974 diagnostic reclassification specified individuals receiving two or more antituberculosis drugs as "cases", most antimycobacterial drugs are not recommended for other uses, hospital pharmacies are converting to the unit-dose system, and public sanatoria and chest clinics are no longer the exclusive dispensers of these drugs, a voluntary pilot project was initiated in 1975 which involved two general hospitals. Because feasibility, productivity, and incomplete notification were observed, Baltimore (with the highest incidence of tuberculosis in the continental USA) enacted an ordinance which required all pharmacies to report the issuance of antimycobacterial drugs (including amount, daily dosage, rhythm of administration, and identifying information on the patient and prescribing physician).

Studied were the number of cases identified through this system during a six-month period who: (1) would have been otherwise unreported, (2) were previously "lost", (3) were discovered earlier than through other mechanisms, (4) were receiving inappropriate regimens or had inappropriate changes in their treatment schedules, and (5) were not receiving continuous therapy. Community prescribing habits and the extent to which

antimycobacterial drugs are being utilized for other purposes were assessed to ascertain the need for consultation services and professional educational campaigns.

Data indicate this system will have significant impact: <10% of cases registered over five months were discovered through reporting pharmacies (although a minority of the 209 are thus far incorporated into the program); drug utilization review should improve community patient care: <12% of forms indicate major errors in the use of antituberculosis drugs.

Pharmacy notification has been evaluated as a means to surveille, contain, and assess a control program within the context of the changing scene of tuberculosis.

Baltimore City Ordinance Number 45 was passed in 1976 (reprinted on page 11) and requires that pharmacists who dispense certain drugs used in the treatment of Tuberculosis report to the Baltimore City Health Department on the Reporting Form shown at right. Representatives from the Baltimore Metropolitan Pharmaceutical Association have met with David Glasser, M.D., Director of the Bureau of Disease Control for the City Health Department in an attempt to determine the necessity for this reporting mechanism. Many Pharmacists have commented that this represents an unfortunate precedent and intrusion upon their practice for which they will not receive remuneration. The penalty provision of the Ordinance has come under heavy criticism.

Members of the Health Department are currently contacting all Baltimore City pharmacies to explain the requirements and the use of the Reporting Form.

#### BILL NO. 103 ORDINANCE NO. 45

An Ordinance to add new Section 240G to Article 11 of the Baltimore City Code (1966 Edition), title "Health," subtitle "Reportable Diseases," requiring pharmacies to report to the Commissioner of Health the issuance of antituberculosis drugs, declaring such records confidential, authorizing inspection by the Commissioner of pertinent Pharmacy Records, and providing penalties.

SECTION 1. Be it ordained by the Mayor and City Council of Baltimore, That new Section 240G be and it is hereby added to Article 11 of the Baltimore City Code (1966 Edition), title "Health," subtitle "Reportable Diseases," to read as follows:

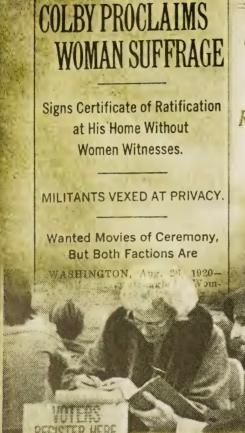
240G. Report of issuance of drugs suggestive or indicative of the treatment of tuberculosis

- (a) Duty to notify Commissioner of Health.—It shall be the duty of any person who is in charge of any public, private, hospital or institutional pharmacy which issues isoniazid, ethambutol, rifampin, pyrazinamide, ethionamide, cycloserine, viomycin, capreomycin, or any other anti-tuberculosis drugs as may be specified by the Commissioner of Health to report such prescription within 48 hours to the Commissioner of Health. This requirement shall not apply to specified drugs issued by facilities operated by the Baltimore City Health Department.
- (b) Contents of notice. Each notification shall be in writing on a form provided by the Baltimore City Health Deprtment, and shall include the date, type, and denomination of medication issued, the daily dosage, the rhythm of administration, the total amount prescribed, and the name, age, sex and address of residence of the person for whom the drug was prescribed, and the name and address of the attending physician for whom such prescription was issued.

- (c) Pharmacy notification shall not be construed as diagnosis. The prescription of drugs with specific indications, though it may be an essential aid to diagnosis, shall not be considered to constitute a diagnosis, and shall not absolve the attending physician from reporting the case under the provisions of Section 223 of this subtitle.
- (d) Contacting patient, discussion with attending physician. The Commissioner of Health or a duly authorized agent shall not contact the patient without the knowledge of the attending physician, when there is an attending physician, and when he is reasonably available. Nothing in this section, however, shall preclude discussion of the pharmacy notification with the attending physician, by the Commissioner of Health or a duly authorized agent.
- (e) Report confidential. All pharmacy notifications herein required shall be confidential and shall not be open to public inspection.
- (f) Pharmacy review. The Commissioner of Health or a designated agent thereof shall be authorized to inspect pertinent records of any facility covered by this section which are deemed necessary to determine compliance with this section.
- (g) Any person who violates the provisions of this section shall be subject to a penalty of not less than \$25 and not more than \$200 for each offense.
- SEC. 2. And be it further ordained that this ordinance shall take effect thirty days from the date of its passage.

### Reporting Form

ATTACHMENT II  1. THE OR FR. M. USING BALL FORM FEN. PRESS. FIRMLY  1. REMOVE C. MIDON. MIRE COMPLETING, COM.  1. RETAIN THRANKET, COM.  + FORMED BALLAKE OF SET TO THE BALTIMORE CITY HEALTH OPPARTMENT.						
CITY OF BALTIMORE HEALTH DEPARTMENT BUREAU OF DISEASE CONTI	REPORT OF ISSUANCE OF ANTI-MYCOBACTERIAL DRUGS In accordance with Section 2408 of Articl of the Baltimore City Code (1986 Editic		HOSPITAL IDENTIFICATION NUMBER (if applicable)		PHARMACY PRESCRIPTION NO.	
PATIENT'S NAME - LAST, FIRST, MIDDLE INI STREET ADDRESS		DATE OF BIRTH MO. DAY	YR. SEX		OTHER  Specify	LACE
NAME & ADDRESS OF REPORTING PRESERVAL  ADDRESS AND DESPITAL WARD IT APPLICABLE  ETC., 100ML REC., STATE  ETC., 100ML REC.						
V DRUG (S) DISPENSED	MILLIGRAM CONTENT OF DISPENSED MEDICATION	N CAPSULE:	OTAL NUMBER NSED TABLETS, S, OR VIALS OF CATED AT LEFT.		AILY RHYTHM DMINISTRATION	THER
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ETHAMBUTOL (EMB)	□ 100 mg / □	400 mg		0 [		0
RIFAMPIN (RMP)	□ 300 mg / ○	g		0 0		0
- STREPTOMYCIN (SM)	□1000 mg / □	5000 mg		010		
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ETHIONAMIDE (ETA)	□ 250 mg / ○ .	mg		0 [		(
PYRAZINAMIDE (PZA)	□ 500 mg / ○	mg		0 [		0
CYCLOSERINE (CS)	□ 250 mg / ○	mg		0 [		0
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# Social Security Bill Is Signed Gives Pensions to Aged, Jo

Roosevelt Approves Message Intended to Benefit 30 Persons When States Adopt Cooperating Laws-H the Measure 'Cornerstone' of His Economic Prog

# SENATE APPROVES 18-YEAR OLD VOTE **INALL ELECTIONS**

Amendment to Constitution is Sent to House. Where Passage is Expected

WASHINGTON, March 10, 1971-The Senate approved

WASHINGTON, Aug

The Social Security Bil a broad program of une

insurance and old ag

and counted upon to b

20,000,000 persons, beca

day when it was signe

dent Roosevelt in the those chiefly responsib ting it through Congre Mr. Roosevelt cal

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# TRUMAN CLOSES NITED NATIONS CONFEREN WITH PLEA TO TRANSLATE CHARTER INTO DEEDS

# NEW WORLD HOPE

President Hails 'Great Instrument of Peace.' Insists It Be Used

HISTORIC LANDMARK

Meeting Gives Standing **Ovation as Executive Pictures Peace Gain** 

"If we fail to use it," he declared to the solemn final meeting of the delegates, 'we shall betray all of those who have died in order that we might meet here in freedom and safety to create it." If we seek to use it selfishly—for the advantage of any one nation or any small group of nations—we shall be equally guilty of that betrayal."

Fervent Interpolation
The President, speaking in the auditorium of the War Memorial Opera House, built in memory of sons of the Golden Gate city who gave their lives in the first World War, in which he himself served, seemed to give unconscious expression to the solemn feeling of the occasion when, at the outset of his speech, he interpolated the words, half a hope, half a prayer:

"Oh, what a great day this can be in history!"
Just before the plenary session the President accompanied the cipht United States delecates to

rne Dra Ends No WASHINGTON, Jan. 27, 1973-"With the signing of

the peace agreement in

Paris today, and after receiving a report from the Secretary of the Army that

# PATIENT PACKAGE INSERTS: A CONCEPT WHOSE TIME HAS COME?

The consumer's right to know is an irreversible and desirable trend of the Seventies. It extends, and properly, to a patient's right to know more about his or her prescription medications. One way, gaining favor, is through patient package inserts. Wisely-prepared and properly distributed when medically indicated, they could markedly improve patient knowledge and drug therapy—laudable goals by anyone's standards.

The PMA endorses these goals and will work with government, the health professions and consumers to achieve them.

#### The Advantages

The concept holds promise of benefits: better patient understanding of the product prescribed, better adherence to the treatment plan, and more awareness of possible side reactions.

Every doctor has had patients who fail to finish antibiotic regimens because they feel better. Some patients assume that if one tranquilizer or analgesic is good, two may be twice as good. Still others fail to report dizziness while on antihypertensive therapy—and so on.

Problems like these might arise less often if the patient received written information in addition to verbal instructions. Some studies suggest that patients are more receptive to such materials, and they more often understand the verbal instructions and follow them, when inserts are used.

### The Disadvantages

There are also some potential problems. Obviously, the inserts must be clearly phrased, without extraneous or complex detail. How much information is enough? How can it be kept current? Should all patients receive the same information? Should inserts be included with all drugs? Should only potential problems be listed or are patients better off with a "fair balance" presentation that describes usefulness as well as drawbacks?

These and similar questions require answers, since model inserts have yet to be properly developed and tested. Despite the need for these studies, the FDA is proceeding prematurely with inserts on selected products. We think the Congress is the only place where the matter can be given the proper legal status and direction, particularly since it represents a conceptual change in the legal, medical and social framework of the nation's prescription drug information system.

#### The Solution

The PMA believes that carefully-devised pilot studies of various kinds of inserts are needed. They should be developed and implemented with full participation by doctors, pharmacists, consumers, communications experts and the drug industry. Such studies will provide reliable pathways to follow, so that inserts will be useful aids to medical practice.

And particularly we think that you should be closely involved in this debate and in these studies and decisions. Otherwise, people with less experience and qualifications may control the purposes, content and use of a tool with considerable promise for improved patient care. It could make a difference in your practice tomorrow, and more importantly, in the health of your patients.

PMA

THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION 1155 FIFTEENTH ST., N. W., WASHINGTON, D. C. 20005

the polygraph test and no one would be discharged or refused advancement for failure to submit to this test. Since that time, several meetings of the Employee Relations committee have shown a lessening of the problem in this area. I would like to thank Ed Nussbaum, Paul Freiman, and the other members of the Committee for their cooperative spirit and regular attendance at these meetings. Hopefully, Rite-Aid pharmacists will become a strong segment of our organization.

Another active Committee, the Industry Relations Committee, showed much industry in its plans and accomplishments. George Stevenson is to be congratulated on the programs, meetings, and inroads made in establishing this vital link with industry. Now policies are being promoted for standardized labeling and return procedures with manufacturers. In this respect, I would like to express my thanks to Mel Rubin for his foresight in establishing the Committee, as well as its very active members.

Other active committees include the Professional Education Committee, with Henry Seidman chairing and Phil Cogan as chairman of the Seminars. Regional meetings were coupled with the Seminars to abbreviate activities in our busy time schedules and I feel we have made a step in the right direction. Too often we are faced with frequent meetings and must make a choice of which to attend. Now we are able to double up and not lose the benefit of these valuable programs.

Our Legislative Committee worked on the new Pharmacy Practice Act which was developed under leadership of Paul Cuzmanes and introduced in part this year. Because the administration was working on comprehensive reforms, this bill was not acted on but some of the provisions were considered. This will continue to be an important area in Annapolis for the next several years. Another set-back was suffered when the Continuing Education bill endorsed by all segments of the profession before filing, was held up at the last minute when the Maryland Association of Chain Drug Stores asked that the bill be delayed one year. We will continue to work for enactment in the next legislative sessions. Of interest also in area of legislation, a bill to allow indiscriminate numbers of consumer members to boards was passed by the legislature. Much persuasion from all professions, including our own MPhA correspondence to the Governor, brought about the veto of this badly worded bill. Most likely it will become law next year when it is written in better form. Bills which will have a direct application include the definition of Pharmacy Practice and establishing Board of Pharmacy disciplinary power in certain defined areas. During the year, concerted efforts to bring about an increase of the Medicaid Reimbursement fee have resulted in a survey bing conducted by Myers & Stauffer to determine the cost of filling a prescription. This survey is being watched across the country as a landmark in establishing fees for other states and for third party programs in general. An interim fee increase to \$2.45 was adopted by the state, but it is unfortunate that this token increase does not match the

increase in fee obtained in the District of Columbia which obtained an increase of 75¢ to a fee of \$2.59. This was a direct result of broad based refusal to fill prescriptions below cost as in the past.

Another slap in the face comes from Blue Cross of Maryland in making a token increase in its dispensing fee to \$2.25, even as the state announces \$2.45. The MAC program has continued to erode any gains in fees obtained from the state and I would like to thank Marvin Friedman, Don Schumer, Mel Rubin, and others who have worked so hard for many years to bring this to the proper officials for their attention.

Our convention and tours committee has arranged several trips for the coming year and I would urge early reservations. Some of my friends missed the last trip due to late attempts to register. Ron Lubman is to be congratulated on his fine work and for the excellent programs for our conventions year after year.

Many of our committees work behind the scenes and I would like to thank Vic Morganroth, Joe Dorsch, S. Ben Friedman, Charles Spigelmire, Sam Lichter, Elwin Alpern, Paul Freiman, Stan Yaffe and Irvin Kamenetz and all others previously mentioned in this report. No president could leave office without thanking those unsung heroes of the office staff. Sharon Spies has been an invaluable addition this year and Mary Ann Frank continues to provide complete, informative reports with her bookkeeping efforts. Also Joan Hurlock has kept our membership records in good order.

The Board of Trustees has reviewed minutes and correspondence on a regular basis prior to board meetings. This year we have been the best informed Board ever. Meetings have been shorter because of advance planning and the manner in which our chairman has conducted meetings. I would like to again express my appreciation to Mel Rubin as my inspiration and my man in Baltimore. He has done everything a president could hope for in his willingness to accept appointments and tasks. I would also like to thank Dave Banta who took over the reins of administration without any let-up in our operation. We are now a viable force in the profession and will continue to be a leader among associations in this country.

Maryland PharmPAC has worked actively to watch the interests of the profession within the state and now a PharmPAC has been formed on a national level with myself as its Treasurer. It would be well for all pharmacists to become active in politics and aware of legislation affecting our practice. No one currently serves in our state legislature from our profession. This might explain why so many poorly thought out bills affecting us are introduced.

I have one final recommendation. This Association is approaching its centennial anniversary in only four years. I would suggest that some thought be given to appointing a committee to begin planning for this historic event.

I would like to thank the Association for having elected me to serve. It has been an honor and it is certainly a privilege to represent such a fine group.

# Liability Protection (It comes with every tablet you dispense)

A recent article on pharmacy law stated that "it is not unlikely that pharmacists substituting therapeutically or bioequivalent drugs for those prescribed will face increasing confrontation in the courts on the issue of their liability for unanticipated or ad-

verse reactions from drugs dispensed by them"\*

It should be reassuring to know, therefore, that McNeil Laboratories stands behind you every time that you fill a prescription for TYLENOL® with Codeine tablets or elixir—and, for that matter, for every McNeil product you dispense. The "McNeil Pharmacist Protection Policy" gives you this assurance. (If you don't already have a

copy, you might like to send for one.)

With the many problems facing the pharmacist today, why risk unnecessary liability problems.

\*From a special report reprinted from U.S. Pharmacist 2(4):18-23, 1977: "Pharmacy Law," by Michael R. Sonnenreich, J.D.



Dispense with confidence...Dispense the leader

McNEIL

McNeil Laboratories, McNEil AB, Inc., Fort Washington, Pa. 19034 TYLENOL with Codeine tablets are manufactured by McNeil Laboratories Co., Dorado, Puerto Rico. 00646 CMcN 1978

JULY, 1978



# A Year of Change and Growth

Treasurer's Report Anthony Padussis, Treasurer June 20, 1978

Thank you Mr. President. It is a pleasure for me to deliver the 1978 Treasurer's report of the Maryland Pharmaceutical Association. The Association, as you know, tries each year to provide more services and benefits to each individual member. I am sure it is obvious to all of you that we have increased benefits, but at the same time, expenses in general have also risen.

It is the responsibility of the Treasurer to oversee all of the MPhA funds and insure that they are properly utilized and invested. In this task I am assisted by the Finance and Budget Committee, the MPhA staff and the entire MPhA Board of Trustees; and I want to thak them now for their able support.

Ithink that most of you know that this past year was a rather unusual one for the Association. The MPhA incurred a few "one-time" only expenses due to the change in Executive Directors. These factors plus the rising inflation rates and cost of doing business in general were offset by an increase in the membership dues amount. Much of the revenue raised from this increase will be reflected in future reports to the membership since the increase was for the 1978 membership year.

The following comments are taken from figures (in round numbers) of the MPhA financial audit as of December 31, 1977 as prepared by the Association's Certified Public Accountant, Mischa N. Schnider. The Association's total income last year was \$80,900.00, our expenses for that same period were \$78,700.00. This results in a net income to the Association of \$2,200.00 which will be added to an accumulation of unappropriated funds for our reserve.

While we are not satisfied with the amount of excess over expenses, I am confident the future is bright for the Association. Association expenses have been held in check as much as possible and income levels for the new year to date appear to be ahead of predicted levels. Even so, recent events, such as the postage increase will mean that the Association must fight to continue to gain a secure financial position.

I would like to emphasize that the key to increasing revenue, in order to increase benefits, is an ever increasing membership. This is a responsibility that falls on each and every one of us.

In these days of uncertainty and unexpected contingencies, it is absolutely essential that the Association develop and maintain a viable reserve fund from which to draw in the event of an unforeseen emergency. I believe that we have made a good start on building such a fund, but that we will need the assistance of every pharmacist willing to show his support of our cause through membership in the Association.

Copies of the official audit are available to any Association member upon request at the Association office.

It has been my very great privilege to serve you as Treasurer of the MPhA during the past years. If you believe that the Association is doing a good job for you, tell a non-member and ask him to join us. If you don't think we are doing a good job for you, tell us and let us make every effort we can to improve. But in the end, we obviously need to unite in ever increasing numbers to prepare for the monumental tasks that are ahead. With your help, we can do it; and our Association's financial future will be secured.

Thank you.

Anthony Padussis Treasurer





July 20 & 27 — BMPA CPR course, Towson Library Branch

July 31 & Aug. 1 — F. A. Davis Show, Martin's West Sept. 17 — MPhA Dinner Theatre — Colony Seven

Sept. 17-21 — NARD Convention, New Orleans

Oct. 5 — Balassone Memorial Lecture

Oct. 16 — MPhA trip to Monte Carlo

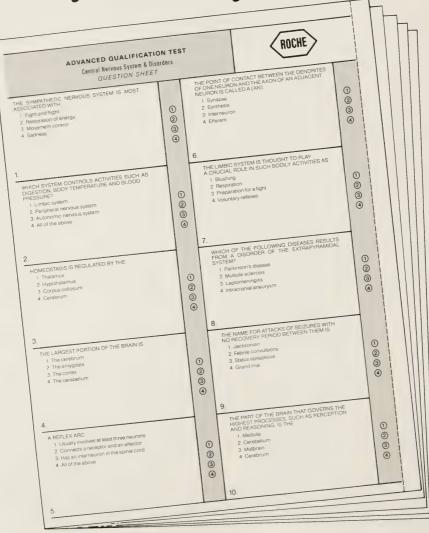
Oct. 29 — Alumni Assn. Oyster Roast

Jan. 13 — MPhA Winter trip to St. Martins

# No. 4 in a series.

# Your Roche Representative has to answer some pretty tough questions.

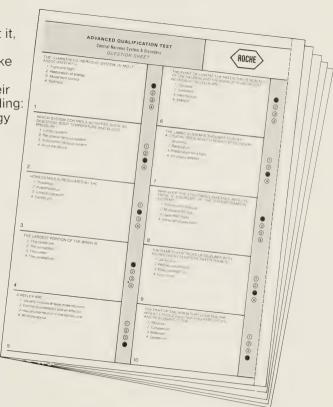
Try a few on yourself.



# Your Roche Representative scores 80% or better.

We think that a company can only be as good as the people who represent it. which is why we insist on excellence from our representatives. And we make sure the standard of excellence is maintained by periodically testing their knowledge in a variety of areas including: the anatomy, physiology and pathology of key body systems, general and product pharmacology and such product information as indications. dosages and adverse reactions. All Roche Representatives must maintain a minimum of an 80% score. But it doesn't stop there. We expect our representatives to be just as knowledgeable about all products in the same therapeutic categories

At Roche, the pursuit of excellence is a way of life.



as our own.

# WIC Program available to Pharmacies

Vendors of infant formula and food may participate in a federally-funded program called the WIC program (Special Supplemental Food Progaram for Women, Infants and Children) which makes available to pregnant women and young children monthly supplies of ironfortified infant formulas, milk or cheese, iron-fortified cereal, eggs and fruit juice. The food is made available by means of negotiable food instrumets (like bank checks) which may be redeemed for kinds and amounts of food specified on the face of the instrument by authorized vendors, and deposited immediately with their receipts. The basis for the price will be the vendor's usual and customary charge.

About 8000 WIC recipients are presently issued food instruments in Montgomery, Prince Georges, Howard, Carroll, Garrett, Worcester and Somerset Counties and a small portion of northwest Baltimore City. Other parts of the state participate in the program, but make the foods available by home delivery.

Federal program regulations require that a local WIC program establish written agreements with participating vendors; a vendor who does not have an agreement will not be reimbursed for food instruments he may have accepted. There are no reporting requirements, but vendors must provide specified foods only, accept and deposit the instruments within specified time intervals, and abide by federal and state program regulations which will be explained to them.

The counties mentioned have previously used some sort of voucher in their WIC programs, but a new computerized food delivery system with a standard statewide voucher will be initiated in August, so vendor agreements will be established in July. For information about participating in the program, contact your county at the number listed below.

Participating vendors will have immediate reimbursement for the foods they have supplied, and it is likely that clients presenting the vouchers will purchase other items at the same time. The new voucher system is expected to benefit the client, the vendor and the community.

Area	Person	Phone
Montgomery Co.	Linda Goldsholl	279-1610
Prince Georges Co.	Jackie Herson	927-4810
Howard Co.	Barbara Keilson	992-2333
Carroll Co.	Karen Stansbury	857-5000, ext. 216
Garrett Co.	Ella Tall	334-8111
Worcester and		
Somerset Co.	Marcia Dixon	749-1218
Constant Care Community	/	
Health Center (N.W.		
Baltimore City)	Barbara Owings	523-6900, ext. 56

# Two new firsts from District Photo!

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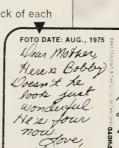
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# Board of Trustees Report

#### Board of Trustees Report Annual Convention — June 1978

Melvin N. Rubin, Chairman

I would like to thank the majority of Board members who attended and participated in most of the meetings during my term as Chairman. Unfortunately, the harsh winter made it difficult for members from outlying areas to attend part of the time.

Past Presidents were added to the mailing list for Board meetings and proved to be the asset we anticipated. In particular, Frank Block and Paul Freiman were active in almost every discussion. Dean Kinnard also added greatly to the sessions.

Meetings were of shorter duration than in past years due partly to the willingness of the Board to come to grips with the issues directly, and in part to the attention given to preparing information by new Executive Director Banta, who also was able to disseminate minutes and meeting notices and material in time for meaningful study.

Since it is the charge of the Board to make decisions for the Association between sessions of the House of Delegates, a recounting of all the Board activities would usurp reports of the Committee Chairmen and officers, so I will simply mention a few of the areas we dwelt on during the year.

The first part of the Association year, the Board dealt primarily with internal affairs, such as finances including setting the summer dinner theater as an annual fund raiser, reorganizing classifications of membership and authorizing needed improvements to the building. A lot of time was spent discussing the proposed revisions in the Pharmacy Practice Act which ultimately was introduced in legislature only in portions. Monitoring the Medicaid Survey as it was accepted by the State, and other third party activities also were dealt with extensively by the Board, including insisting that the MPhA no longer administer the Esskay program unless they significantly increased their fee to pharmacists. During the year the fee was increased from \$1.85 to \$2.45 and a review promised for early 1979.

The Board accepted the work of the Industry Relations committee concerning uniform labeling and a model return goods policy, and also approved the Blue Cross major medical program and the Professional Protector Insurance Plan, both of which have been offered to members. Board members had the opportunity to have input on the proposed format for dispensing information in USP XX.

In one of the most significant decisions, the Board voted to extend the Association policy of offering support for legal activities necessary to insure adequate medicaid fee, to supporting activities to insure equity from all third party carriers. Board approved participating with MSHP in an in depth study of the use of pharmacy aides, and reinstituted the John F. Wannenwetsch Scholarship Fund, to be financed by voluntary contribution.

In the last meeting of the year the Board voted to recommend to the House of Delegates that MPhA accept the offer of APhA for a 24 month moratorium on joint membership requirement. This will lay to rest the argument of whether this has caused any pharmacists to refrain from joining the MPhA.

# Classified Ads

Classified ads are a complimentary service for members.

(send replies addressed: ad no. \_\_\_\_\_, M.Ph.A., 650 West Lombard St., Baltimore, Md. 21201)

#### Office Space Available

Bel-Joppa Square — new Perry Hall mini-convenience center — 1500-3000 ft. — now leasing for Sept. occupancy. Hess Realty, Inc. 668-3000.

#### Position Available

Full time — Rea & Derick, Inc., pharmacist & assistant manager — store is in the Frances Scott Key Shopping Center in Frederick, Md. Contact either Mr. Hurst or Mr. Shook (717) 473-3511.

#### Available From MPhA Office

Available free to members, notification form to be given to patient under drug product selection law. Call Sharon (301) 727-0746.

# **APhA/ASHP Joint Communication**

There are two main areas in which pharmacists will become involved in P.S.R.O. review activities: review of how drugs are being utilized (drug use review); and review of pharmaceutical services (e.g., drug distribution systems). Drug use review activities will usually be tied in with P.S.R.O.-mandated Medical Care Evaluation (MCE) studies while the pharmaceutical services review efforts will be part of the overall "ancillary services review" under the P.S.R.O. program. Drug use review is a shared activity of the medicine and pharmacy professions, whereas pharmaceutical services review is a peer review responsibility of the pharmacy profession.

"Delegated review status" under P.S.R.O. allows an institution to conduct its own review programs rather than having the P.S.R.O. carry out the review. This, we believe, is "the way to go." Delegated review status can be obtained if the institution can demonstrate to the P.S.R.O. that its review programs are of adequate quality and meet P.S.R.O. specifications.

For more information or answers to specific questions related to drug utilization review write to: APhA's Professional Affairs Division or ASHP's Director of Professional and Scientific Affairs.

#### BACKGROUND

The Social Security Amendments of 1972 (PL 92-603) established Professional Standards Review Organizations (PSROs), which are responsible for the review of all institutional services, with priority to be given to the review of hospital care. Since the use of medications is an important component of hospital care, pharmacists are among the health care practitioners other than physicians who are eligible for participation in PSROs.

The American Pharmaceutical Association and the American Society of Hospital Pharmacists have encouraged pharmacists to participate in PSROs, specifically through the mechanism of drug utilization review (DUR). Development of drug utilization review is a responsibility shared jointly by the physician and pharmacist. Both APhA and ASHP feel this type of study is very valuable, and can contribute significantly to the quality of health care provided in institutions.

#### **OBJECTIVES OF DUR**

- 1. To apply the principles of utilization review to the drug component of health care.
- To increase the quality of drug treatment by promoting rational prescribing.
- 3. To assure the safety of prescribing and administering medications to patients.
- To establish standards on a drug-by-drug basis to define the various parameters of rational prescribing and usage.
- 5. To review, analyze and interpret patterns of drug usage.
- To expedite the drug aspect of peer review for physicians.

#### CHARACTERISTICS OF DUR

DUR can be described as a quality assurance program for drug therapy. A patient medication profile system, when utilized properly to screen for drug interactions and inappropriate therapy, can be considered a rudimentary DUR. To assure quality, however, DUR should be a structured and continuing program that reviews, analyzes and interprets patterns of drug usage in a health care delivery system against predetermined standards. DUR should be locally implemented, on a voluntary basis, and the persons responsible for DUR studies should adopt an impersonal approach to problem solving.

DUR need not be a highly comprehensive and time consuming exercise. For example, evaluation of one or more of the following criteria could constitute an effective DUR study:

Polypharmacy (e.g., Use of 2 or more antibiotics/ anti-infectives concurrently)

Daily dose of drug

Length of treatment

Appropriateness of drug prescribed for diagnosis

Non-approved uses of drug

Necessity of drug

Use of irrational combination drug products

Drug interactions

Utilization of non-formulary drugs

Utilization of drugs other than the drug of choice

Medication errors (time of administration, etc.)

# on Drug Utilization Review

Basically, then, any drug, use of a drug, or drugrelated problem could be the basis of an effective and useful DUR study.

The final characteristic is education. When the results of the DUR study are compiled, the prescribers, medication nurses (or medication administration technicians) and pharmacy staff, as appropriate, should be MADE AWARE OF THE RESULTS. Constructive recommendations should be made to solve the problem (s) identified and follow-up DUR studies conducted to determine the effectiveness of the educational process.

#### MISCONCEPTIONS ABOUT DUR

There are two common misconceptions about DUR. First, DUR is not a mechanism for cutting drug costs within the institution. This is not to say that decreased costs will not be realized as a result of an effective DUR program. However, any financial savings should be considered a beneficial side effect.

Secondly, the results of a DUR study are meant to be used for educational purposes only, not as a basis for taking punitive measures against the prescriber, nurse, or pharmacist. DUR studies are impersonal, objective studies to promote rational drug therapy, contributing to better patient care.

#### REFERENCES

The programs and publications listed below are available to assist in developing drug utilization review and quality assurance programs for hospital pharmacy.

1. "GUIDELINES FOR DRUG USE REVIEW IN MENTAL HEALTH CARE FACILITIES" contains basic information and guidelines on developing drug use review programs. Though specifically directed at mental health care facilities, it is applicable to all types of institutions. Single copies (approximately 90 pp., typewritten) are available upon request from Dr. Alvira Brands, National Institute of Mental Health, Room 11-105, 5600 Fishers Lane, Rockville, Maryland 20857.

- 2. "DRUG UTILIZATION REVIEW IN SKILLED NURSING FACILITIES" describes a system for conducting drug use review studies in SNFs which will meet MCE study requirements. Protocols for conducting MCE studies on ten different drugs are included. Copies of the book (126 pp., typewritten) are available for \$1.95 from the U.S. Government Printing Office, Washington, D. C. 20402.
- 3. A MANUAL SYSTEM FOR DRUG USE REVIEW describes a means for beginning a system of drug use review in an organized setting. The system has been tested in a number of neighborhood health centers differing in size, sophistication, and type of pharmacy program. It has proven to be sound and versatile, yielding a comprehensive picture of drug use trends and prescribing patterns, and providing information necessary to optimize the quality and efficiency of the drug component of medical care. This manual is available from the APhA Order Desk, 2215 Constitution Avenue, N.W., Washington, D.C. 20037 for \$5.00.
- 4. The "MODEL QUALITY ASSURANCE PROGRAM FOR HOSPITAL PHARMACIES" Manual provides an example of one approach to a program for assuring the quality of pharmaceutical services (other than drug therapy) in hospitals. Copies are available from the American Society of Hospital Pharmacists, 4630 Montgomery Avenue, Bethesda, Maryland 20014 for \$25.00 each.
- 5. "ANTIBIOTIC USE REVIEW AND INFECTION CONTROL: EVALUATING DRUG USE THROUGH PATIENT CARE AUDIT" is a two-day program conducted by the American Society of Hospital Pharmacists and InterQual, Inc., which will enable institutional pharmacists to participate in the drug use review component of patient care audit. Two programs will be conducted: May 1-3 in Boston, Massachusetts; and September 25-27 in Portland, Oregon. Program information is available from ASHP.

In addition, a companion manual of the same title developed for use with one institute is available from the American Society of Hospital Pharmacists for \$30.00 each.

Dear Pharmacist: The B.W. Co. Pharmacy Education Program is now bigger and better than ever!



# We've committed a total of \$325,000 to the pharmacy schools of your choice.

## We've "upped" our commitment to the future

When the total number of awards for the past five years is tabulated at the end of 1978 it will total \$325,000.

And next year, 1979, our contribution will significantly increase that amount. The Burroughs Wellcome Co. Pharmacy Education Program is another way we support pharmacy.

# We've "upped" the grant to \$750...there are three winners from each state

Three registered pharmacists from each state, plus D.C. and Puerto Rico, will have the opportunity to present an education grant in their names to the pharmacy colleges of their choice. Burroughs Wellcome Co. is pleased to express its commitment to your profession by raising the amount of each grant from \$500 to \$750. These grants establish permanent revolving student loan funds to help deserving pharmacy students complete their studies. Every registered pharmacist in the country is eligible, including those in D.C. and Puerto Rico.

# Drawings to be held at the N.A.R.D. Convention

Convention dates: Week of September 18, 1978. Location: New Orleans, Louisiana. You need not be present in order to win.

## Winners will be publicly announced

Your generosity will be publicly acknowledged in your community. Each winner will receive a suitably inscribed plaque in commemoration of his grant.

## Other B.W. Co. programs for the benefit of pharmacy

- Product liability protection for pharmacists properly dispensing B.W. Co. products.
- Liberal "Returned Goods" policy.
- Education programs for practicing and student pharmacists.
- Wellcome Trends in Pharmacy, a news periodical of important professional developments.
- The Silas M. Burroughs Memorial Fellowship and The Henry S. Wellcome Memorial Fellowship, granted for graduate research in pharmacy.
- Summer employment for undergraduate pharmacy students at our production facilities in Greenville, North Carolina.

**Everyone who enters will** receive a free Wellcome Tablet **Counting Tray.** Watch your mail for entry blanks.



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# **Optimism for the Future**

#### Executive Director's Report Annual Convention — June 1978

It hardly seems possible that we are approaching the anniversary of my association with Maryland Pharmaceutical Association. The past year has rapidly fled leaving its share of triumphs and challenges for the Association. Many of the MPhA's recent activities have been detailed for you by previous speakers; so I will take only a minute now to point out what I think will prove to be the most significant events that have taken place since the last convention.

Early last year, the Association found itself in a tangle of assorted membership categories with a whole range of various dues categories. The Finance and Budget Committee quickly devised a straightforward dues alignment procedure which has streamlined the membership categories and made internal record keeping much more practical.

Another historical milestone was reached with the final implementation of last year's Drug Product Selection law. Members of the Association have labored for years for this success. However, the ultimate outcome in terms of public recognition of our professional abilities in this area is still undecided. In this regard, it is up to each pharmacist to exercise professional judgement, and just as importantly, inform the public that a professional prerogative has been used.

Most of you are well aware of our fine year in the legislature. I won't detail the outcome of the various bills we were following. However, I do believe that the passage of the new definition of the practice of pharmacy will have far reaching effects for the profession. It may well allow pharmacists in the future to expand the scope of the practice in Maryland as the need develops.

I personally was very pleased with the fight for the Continuing Education Bill in the last session of the general assembly. For, although we lost the bill in Senate Committee, we saw the uniting of all of the various groups within organized Maryland pharmacy to support, or at least not oppose the passage of this bill. I believe that next year we will see the passage of a good C. E. Bill.

In the area of membership fringe benefits, the Association added the Blue Cross/Blue Shield major medical health insurance program. I am certain this will expand in future years to be one of our most prominent benefits and will attract a number of non-members into the Association.

I know you will hear a lot more about the third party crisis which we now face and the proposed solutions. We should, however, not lose sight of the fact that members of this Association have been successful in raising the dispensing fee from \$2.00 to \$2.45 in a comparatively short time. And, although this is still far from sufficient to make up for concurrent cuts by the state through the MAC program and the general erosion of profits, this kind of activity is the envy of pharmacists in other states.

Another significant event was the commitment of the state to conduct a prescription cost survey through the accounting firm of Myers & Stauffer. In the very near future, the results of this survey will be final and the Association will be in a good position to justify another adjustment of the dispensing fee under medicaid.

As most of you who know me are aware, I tend to be an optimist. I think you have to be to pursue Association management successfully. I have been encouraged by the progress that the Association has made during the past year and I feel our future is bright. I have genuinely enjoyed working for the pharmacists of Maryland and I sincerely appreciate the support I have received from the members in terms of time, effort and enthusiasm.

As we look ahead to next year I have several personal goals that I am hopeful we can attain.

I would like to see a better utilization of the Kelly Memorial Building. I have attempted to expand the exposure of the building to pharmacy organizations of all kinds, and I hope that in the near future, we can receive some public recognition for this historic facility.

I hope to continue to expand on the excellent start we have in improving relationships between the MPhA and the various component and organized pharmacy groups within the state. Through this kind of cooperation, we will all ultimately reach our common objectives of improving the profession of pharmacy.

The Association will also continue its successful efforts to increase membership in the MPhA while concurrently increasing the services and benefits which the Association offers members. We must build a strong financial base and reserve if we are to deal with the uncertain contingencies of the future. . .

I wish to thank the Officers, Board of Trustees and Committee members for all of the help and encouragement they have given me during this year. Pharmacists throughout Maryland, have been helpful to me and I have developed many friendships as a result.

I especially want to thank the office staff for all of their assistance and hard work. Sharon Spies, Joan Hurlock and Mary Ann Frank have done an excellent job for all of you working behind the scenes at the Kelly Memorial Building. Whenever you are in our neighborhood, take the time to stop at 650 West Lombard Street to visit your Association office.

The Association is continuing to grow and I think we can all be proud of this fact while looking ahead to the tasks and challenges of the future.

Thank you.

David A. Banta Executive Director

#### HONOR ROLL OF SUSTAINING MEMBERS

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#### 1978 ANNUAL CONVENTION CONTRIBUTORS

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#### 1978 CONVENTION EXHIBITORS

Blue Cross/Blue Shield of Maryland Food and Drug Administration United States Pharmacopeia Shared Pharmacy Systems Wyeth Drug Company SAPhA, Maryland Chapter

# Recollections

A Medical Scientist Remembers by JOHN C. KRANTZ, JR., PH.D., F.A.C.C.



"Enthusiasm is the golden chain that links effort with achievement and terminates with the satisfaction of a task well done."

J.C.K., Ir.

Foreword by Chauncey D. Leake, Ph.D., Sc.D.

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With both *Micro-Info* and *Redimed* you'll get information on new products, new sales ideas, and the latest news from

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The Alumni Association of the University of Maryland School of Pharmacy held its Graduation Banquet on June 1, 1978 honoring the new pharmacy school graduates. William Weiner (left) receives the Past-President's Plaque from incoming President George Voxakis (right). Henry Seidman, recipient of the Association's Honored Alumnus Award is seated in the foreground.



The incoming officers of the Alumni Association are shown before the installation ceremony.

# **Alumni Association Honors Graduates**

Pictures courtesy Paramount Photo Service

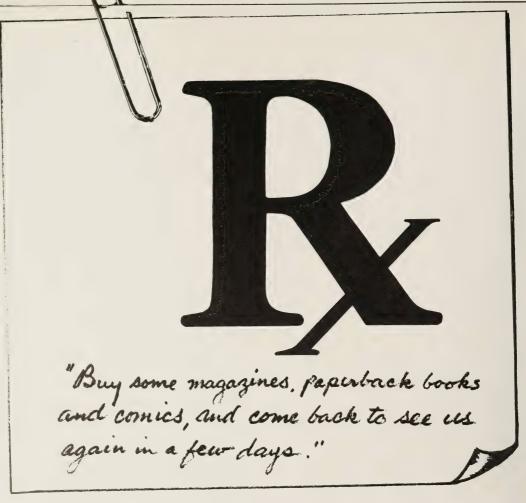


The Annual Banquet, held at Martin's West in Baltimore, was the scene of many reunions among former classmates.



Earlier in the day, the University of Maryland School of Pharmacy held an Honors Day Convocation Ceremony in the Courtyard of the Institute of Psychiatry and Human Behavior. The School granted 88 B.S. degrees and six Pharm.D. degrees. Many of these graduates attended the Banquet in their boor.

29



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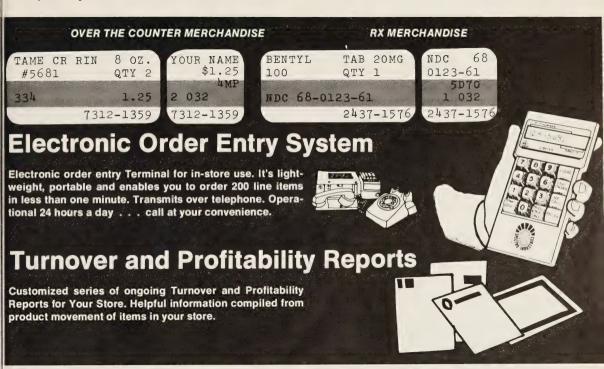
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# A Pharmacy and Therapeutics Committee Report on Desipramine Hydrochloride

Thomas C. Majerus, Pharm.D.
Assistant Professor of Clinical Pharmacy
The Maryland Institute for Emergency Medical Services

- A. Generic Name: Desipramine Hydrochloride
- B. Brand Names and Manufacturers:
- 1. Norpramin by Merrell-National Laboratories. Norpramin is available as coated tablets in 25 mg., 50 mg., 75 mg., 100 mg., and 150 mg. doses.
- 2. Pertofrane by USV. It is available as 25 mg. and 50 mg. capsules.
- C. Manufacturers Recommended Indications:

Desipramine Hydrochloride as indicated for the relief of depressive symptoms. Endogenous depressions are more likely to be alleviated than others.

#### D. Pertinent Pharmacodynamics:

- 1. Administration the drug is not recommended for use in children. Lower doses are recommended for elderly patients and for adolescents. Lower dosages are also recommended for outpatients compared to hospitalized patients who would be under close supervision. Dosage should be initiated at a low level and increased according to clinical response and any evidence of intolerance. Following remission, maintenance medication may be required for a period of time and should be at the lowest dose that will maintain remission.
- 2. Dosage the usual adult dosage is 100 to 200 mg, per day. Dosage should be initiated at a lower level and increased according to tolerance and clinical response to a maximum of 200 mg. per day. Dosages above 200 mg. a day are not recommended. Initial therapy may be administered in divided doses or a single daily dose. Maintenance therapy may also be given on a once daily schedule for patient convenience and compliance (5). The usual adolescence and geriatric doses is 25 to 100 mg. daily. Dosage should be initiated at a lower level and increased according to tolerance and clinical response to a maximum of 100 mg. daily. Dosages above 100 mg. are not recommended in these age groups.

3. Pharmacokinetics — the drug is metabolized in the liver to an inactive metabolite of which about 70% is excreted in the urine.

#### E. Evaluation

Desipramine Hydrochloride is an antidepressant drug of the tricyclic type. The tricyclic antidepressants block the reuptake of the neurotransmitter from the synapse. This results in an increase of the concentration of the neurotransmitter at the receptor site. If depression is presumed to be a result of a deficiency of norepinephrine and/or seritonin in the central nervous system, the increased concentration of the neurotransmitter at the receptor associated with that antidepressant might account for its therapeutic effect (6). During one study (3) it was shown that not all the tricyclic antidepressants have the same inhibitory effect on the reuptake of norepinephrine and seritonin. There were two types of depression noted in this study. In the first group, there was an upset in the metabolism of norepinephrine and no alteration in metabolism of seritonin. In the second group there was an inherent problem with seritonin metabolism and norepinephrine metabolism was normal. In another study (4) the same was found. These studies showed the desipramine selectively inhibits the reuptake of norepinephrine while Amitriptyline selectively inhibits the reuptake of seritonin. In these studies, urinary levels of MHPG which is 3-Methoxy-4-Hydroxyphenethylene glycol and is the major metabolite of brain norepinephrine. In patients who were depressed and excreted significantly less MHPG into their urine than did a healthy comparison group, the remissions were seen in their depression when they were treated with imipramine or desipramine and achieved no response when given amitriptyline. There were no studies done comparing desipramine with doxepin but it is believed that doxepin will act in a similar way to desipramine and is indicated for norepinephrine related depression. In using this drug, then, patients who had normal amounts of MHPG in the urine were treated with both amitriptyline and desipramine and the results showed response to amitriptyline and not to desipramine. Also, patients who had lower

levels of urinary MHPG were treated with both desipramine and amitrintyline and results were seen with desipramine and not with amitriptyline. In using this drug clinically I do not know of a means of measuring urine MHPG levels. However, the clinician might empirically decide to use designamine in place of amitriptyline and vice versa when a response is not seen and by this mechanism sort out which patient would respond to one or the other drug without the added cost of other laboratory tests. In studying the various dosage regimen of the drug (5), it was shown that a single bedtime dose of desipramine was as efficacious as a daily divided dosage regimen. While nothing has been proven to show a decreased incidence of side-effects with a single dose compared with multiple doses, it was shown that compliance was definitely greater in the single daily dose group when compare with the multiple daily dose group. In the body. Impramine is converted to designamine by a demethylation process. In studies comparing designamine with imipramine (1) it was shown that no appreciable deviation between desipramine or imipramine could be distinguished on the basis of clinical response. However, desipramine was responsible for the least number of side effects when compared with imipramine and desipramine was seen in the study to be equipotent with imipramine. In studying the anticholinergic activity of desipramine (2.7) and comparing these side effects with amitriptyline, it was shown that amitriptyline had a significantly greater number of anticholinergic side effects than did the desipramine, but there was not a significantly greater incidence of sedation with amitriptyline when compared with desipramine. In the use of desipramine there were encounters with gastrointestinal upsets, dry mouth, and some drowsiness but in no cases did the patient ask for the medication to be discontinued. There was no significant effects on blood pressure, urine output, or liver function.

The cost of both Norpramin and Pertofrane is approximately 9 to 10 cents per 25 mg. capsule and 16 to 17 cents for the 50 mg. dose.

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#### Pictures courtesy Paramount Photo Service



Vincent Regimenti, President of the Anne Arundel County Pharmaceutical Association presides over a recent meeting.



Pharmacists take notes during the continuing education portion of the meeting which was held on May 11, 1978.



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#### **LETTERS**



Dear Dave:

I'd like to call your attention to a potential problem for Pharmacists who are selling the e.p.t. (early pregnancy test), a new OTC do-it-yourself pregnancy test from Warner-Chilcott.

The Medical Letter (Vol. 20, No. 8, April 21, 1978) calls attention to the relatively high percentages of false-negatives that are given by this test.

Specifically, the results of studies reported by the manufacturer indicate that "the test is highly accurate only for the positive test." That is, if the test reads positive, the patient is most assuredly pregnant. However, when the test indicates the patient is not pregnant (a negative test), upwards of twenty to twenty-five percent are actually pregnant (these are called "false negatives").

As noted in the Medical Letter, other concerns include:

Ecotopic pregnancy and threatened abortion may give false-negative results

Menopausal patients may give false-positive results

Proteinuria may give false-positive results

Patients taking phenothiazines or methadone may yield false-positive results

Although no immunological tests are without some of these concerns, it is important that Pharmacists impress these facts on their patients who are buying e.p.t.

Thought you might want to pass this information on via the Newsletter or Journal.

It might be advisable to get Warner-Chilcott's reaction to this information.

Cordially.

Donald O. Fedder, Pharm.B.S., M.P.H. Director, Community Pharmacy Programs

Dear David:

It was nice talking with you. As you suggested, I am sending you the names of two pharmaceutical reps that can best represent us in the state of Maryland. They are: Hugh Sheridan and Ron Gosser.

I would appreciate your entering the addendum of your May list in the July journal.

Best Regards, Gene W. Self, Manager Distribution & Trade Relations Hoechst-Roussel Pharmaceuticals, Inc.

Dear Mr. Banta:

In recent months many States have passed legislation authorizing Pharmacists to substitute drug products. Since Maryland is among them, it gives Merrell-National Laboratories the opportunity to re-state and explain our policy on assuming pharmacists liability when they dispense any Merrell product.

Here is Merrell-National Laboratories product liability insurance protection statement:

When Merrell-National products are used in properly filling an open or branded prescription, our product liability insurance covers authorized persons handling our products against claims or suits arising from their ultimate use. Coverage included both bodily injury and property damage liability. Our coverage, of course, specifically excludes any person's negligent act or the making of unauthorized express warranties about any Merrell drug.

Merrell stands behind its products and the responsible drug distribution system in the United States.

Merrell stands behind you the dispensing pharmacist every time a Merrell product is lawfully dispensed. This certificate is tangible evidence of our commitment to protect you against claims or suits arising from dispensing of Merrell products. Of course, you must: (a) Give Merrell prompt notice of the suit or claim, (b) Maintain adequate records, and (c) Cooperate fully in our defense of the suit or claim. Write to us for a copy or ask your Merrell salesperson. Since 1828, Merrell has researched, developed, and produced quality pharmaceuticals for the people of this country. Nearly one and a half centuries of excellence is your assurance of trust in each product we manufacture.

You may wish to make our policy known to the Pharmacists in your State by publishing it in the MARY-LAND PHARMACIST.

N. E. Monticelli
Government Affairs Area Manager

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Official Journal of The Maryland Pharmaceutical Association

AUGUST, 1978 VOL. 54 NO. 8



# **Antibiotic Therapy in Geriatrics**

(with special C.E. Quiz)

- Thomas C. Majerus, Pharm.D.

# Joint MPhA/MSHP Statement on Supportive Personnel

1978 Convention highlights in pictures

#### THE MARYLAND PHARMACIST

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AUGUST 1978

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NO. 8

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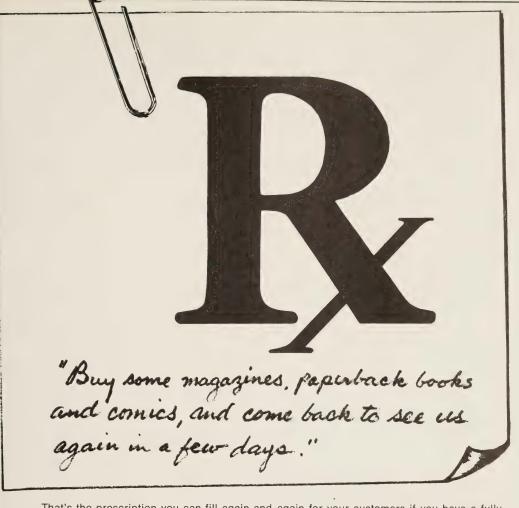
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# Professional Survival Means Political Involvement

It is more and more apparent that, if the profession is to advance in the years ahead, one of the key factors will be how well we represent ourselves and our interests in the political arena. It is not enough for our members to assume that other pharmacists will lead the fight. *Everyone* must act as a spokesman for our cause. There are many things that you can do to help.

- Become active in the Association
- Contribute to PharmPAC
- Attend business meetings and express your viewpoint
- Get involved in political affairs

As our political involvement grows, I am confident that we will eventually have pharmacist representatives in elected state government positions. Pharmacy's voice in politics has progressed in recent years, but it has a long way to go before we can benefit from the maximum impact necessary to insure our survival. I am convinced that the major threat to our profession is the infringement of government over-regulation on the practice of pharmacy. Without significant political involvement by our members, we will not be able to counteract this destructive trend.

I look forward to serving as President of the Maryland Pharmaceutical Association during this term. I want to hear from as many members as possible. Please write to me in care of the Association office if you have any suggestions, comments or problems which you feel we can help with.

Along by John

# **Antibiotic Therapy in Geriatrics**

Thomas C. Majerus, Pharm.D.
Assistant Professor of Clinical Pharmacy
The Maryland Institute for Emergency Medical Services

Geriatric therapy is a developing and dynamic field. Because of advances in medicine, more people are living longer. The percentage of our population that is over 65 years of age is increasing steadily.

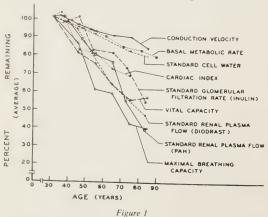
Chronological age and physiological age are not always equivalent. The fact that a person is six decades old does not necessarily mean that his body is functioning at the rate you would expect from sixty years of wear and tear. It may be functioning as though it were a healthy forty years old. Conversely, a person who has just reached thirty years of age, and who, because of lack of care and co-existing chronic disease, is not feeling well, might be trudging through life like a person who is thirty years old going on sixty. Judgment is needed especially when variable response to drugs is observed among elderly patients.

Therefore, it can be said that drug therapy in elderly patients is a function most often of physiology and also of the presence of chronic debilitating disease.

The major considerations with geriatric antimicrobial therapy are listed in Table 1.

#### Immunological and Infectious Considerations

In figure 1, one can see that many physiological parameters in a patient diminish as the patient increases in age. While many of the parameters indicated relate to cardiac function, the two parameters important for anti-

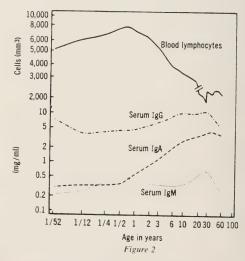


LOSS OF EFFICIENCY WITH AGE OF SEVERAL HUMAN PHYSIOLOGIC FUNCTIONS

Reference: KOHN, R.R.: Human Aging and Disease. J. Chron. Dis. 16:5, 1963

biotic therapy in the elderly are the changes in standard cell water and renal function. The changes in standard cell water are important for drugs that distribute primarily in the body water. Because, total body water diminishes as a percentage of the body weight of the individual, less drug is able to distribute in the body water and the serum level will arise. The changes in renal function are most apparent for those antibiotics that are excreted primarily by the kidney and as kidney function diminishes, the amount of antibiotic cleared from the body by this mechanism also diminishes.

The immune system responds more slowly and less vigorously in the geriatric patient. The general incidence of allergic reaction seems to be less in older patients. A tuberculin skin test may become negative when it was previously positive. IgG and IgM are two of the five immunoglobulins present in the defense system of the body and they are responsible for defense against infec-



AGE-RELATED CHANGES IN BLOOD LYMPHOCYTES
AND THE MAJOR SERUM IMMUNOGLOBULINS
References:

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## CONSIDERATIONS IN GERIATRIC ANTIMICROBIAL THERAPY

- 1) Immunological and Infectious
- 2) Indigenous Microbial Flora
- 3) Renal Function
- 4) Gastric Acidity
- 5) Emptying Rate of Stomach
- 6) Drug Absorption
- 7) Hypersensitivity8) Metabolic Abnormalities

#### INDIGENOUS MICROBIAL FLORA

E. Coli Enterobacter Klebsiella Proteus Pseudomonas

## ANTIMICROBIAL AGENTS EXCRETED RENALLY

PENICILLINS
CEPHALOSPORINS
AMINOGLYCOSIDES
VANCOMYCIN
COLISTIMETHATE
POLYMYXIN
TETRACYCLINES
(Except DOXYCYCLINE)
ETHAMBUTOL
ISONIAZID
FLUCYTOSINE

Table 1

Table 2

Table 3

tion by bacteria and viruses. Serum concentrations of IgG, IgA, and IgM were measured in 811 healthy individuals between the ages of 1 and 92 years. Significant reductions in igG, and IgM concentrations were noted in the older individuals studied.

In figure 2 one can easily ascertain the changes in blood leukocytes and serum IgG and IgM levels in the body as the patient gets older. Because the white blood cells and serum immunoglobulins are the first line of defense once the organism has bypassed the primary body defense mechanism such as skin and mucosa, early diminution in these levels in an older patient will render the patient more susceptible to infection.

#### **Indigenous Microbial Flora**

In table 2, one can see a listing of the indigenous microbial flora to which the elderly seem to be more susceptible than the younger population.

Infections in the elderly tend to be less acute and more latent with less overt and stunning diagnostic signs. Also, the elderly tend to have mixed infections with more than one organism. Where a young person might not have an infection with indigenous flora, the geriatric patient is more susceptible to infection with normal flora, such as E.coli, Enterobacter, Klebsiella, Proteus, and Pseudomonas. The organisms responsible for infection are members of the normal microbial flora that inhabits various areas of the body, especially the upper respiratory and intestinal tracts.

#### Renal Function

Renal function is one of the most important determinants of response to antimicrobial agents. It is not only a major consideration in the choice of a drug, but it also influences selection of a dose and the risk of reactions involving both the kidney and other organs. It is obvious, therefore, that renal function must be monitored before therapy is initiated and throughout the entire period of treatment and possibly for a short time after treatment is completed.

Table 3 lists common antimicrobial agents that are excreted primarily by the kidneys. Whenever a parenteral or oral form of an antibiotic that is excreted by the

kidney is to be used, adjustments in dosages or dosage intervals must be made and at times one might elect to use a different agent altogether. For example, when a patient has severely depressed renal function, nafcillin may be substituted for methicillin. While methicillin is excreted renally, nafcillin is excreted primarily by metabolism in the liver and can become the drug of choice when a semi-synthetic penicillin is desired in a patient with depressed renal function.

When using drugs which are excreted primarily unchanged in patients with compromised renal function, care and judgment must be exercised to avoid high blood levels that will produce toxicity or an exaggerated response.

It is well known that renal function decreases with advanced age. Renal function is poor in newborns (and even worse in premature babies) and does not approach maturity until about one year of age. It is not known when an average adult will begin to have compromised renal function, but it must be emphasized that the presence of normal urine, normal blood urea nitrogen and normal serum creatinine does not guarantee that a person has 100% of his kidney function. Important considerations are the age, muscle mass of the patient and sex of the patient. Serum creatinine has often been used in and of itself to determine kidney function. Creatinine is a product of muscle breakdown and is excreted by the kidney. It is assumed that for many antibiotics, the portion that is excreted by the kidney is excreted at a rate that parallels the excretion of creatinine. In many hospitals and laboratories, however, you will find a different range of normals for serum creatinine. The popular range is from 0.8 to 1.2 mg/deciliter. It must be emphasized once again, that a serum creatinine of 1.1, which is in the normal range, has a much different meaning in the man who is 25 years from that in a man who is 70 years.

Because creatinine clearance is used frequently in assessing the degree of kidney function and since for all practical purposes the clearance of most renally excreted drugs seems to parallel the clearance of creatinine from the body, the creatinine clearance is used in the determination of optimal doses of the many drugs including antibiotics.

In Table 4 we see the use of the first step in the series of formulas for determining creatinine clearance. The first step is to estimate the patient's lean body weight. Lean body weight is used because most antibiotics do not penetrate in other than lean tissue to any appreciable extent. To decide on a patient's lean body weight we need the patient's height in inches and a constant that is derived from the table. In using these formulas, we take the patient's height in inches times two and from this product subtract a constant that is determined depending on the patient's sex and frame. For example, a male who is 72 inches tall and has a medium frame will have a lean body weight of 74 kg. This is simply 72 times 2 minus the constant 70.

#### **ESTIMATION OF LEAN BODY WEIGHT**

 $\label{eq:LBW} \begin{aligned} \mathsf{LBW} &= (\mathsf{2} \times \mathsf{Height}) \longrightarrow \mathsf{K} \\ \mathsf{LBW} &= \mathsf{Kg} \\ \mathsf{Height} &= \mathsf{Inches} \\ \mathsf{K} &= \mathsf{Constant} \end{aligned}$ 

#### TABLE OF CONSTANTS

	MALE	FEMALE
Small frame		76.5*
Medium frame		72
Large frame	65	68

\*This value must be increased by one or two for small-framed women taller than 5'10'' and be reduced by the same for those under 5'.

FROM: RAICHLEN, J.S. (Letter): Calculating Gentamicin Doses. *Ann. Intern. Med.* 85(6): 827-828, Dec. 76.

Table 4

In Table 5 the clearance of endogenous creatinine is then determined. With this formula we use the patient's lean body weight determined previously and his age along with the serum creatinine as it was measured. First, the total creatinine that is manufactured by the body on a daily basis is calculated using the formulas either 1A or 1 B depending on the patient's sex. Next, the patient's more recent serum creatinine is determined. Using the most recent serum creatinine and the total output of creatinine we then determine the patient's average output of creatinine. This is the average output of creatinine because not all the creatinine that has been produced is excreted. It is for this reason that we all have a serum creatinine level at all times within our blood. Equation number 4 using the values for average output and serum creatinine yields a creatinine clearance and the units of this creatinine clearance are in ml. per minute.

As has been mentioned the significance of a serum creatinine varies in different people depending on the patient's age. While a serum creatinine may be in the normal range for two people one of whom is in his 60's and the other in his 20's, the creatinine clearance may be markedly different. In Table 6 you see where a series of patients is presented in whom the only difference is their

age. The lean body weight, sex, and serum creatinine is all equal and by most assessments they would have a "normal" renal function. As can be seen from the example, just by virtue of age, the creatinine clearance diminishes with age and this difference is quite significant once we begin dealing with patients who are greater than 50 years of age. Remember that as creatinine clearance falls, the clearance of drugs that are normally excreted primarily by the kidney also falls.

#### ESTIMATE OF ENDOGENOUS CREATININE CLEARANCE WITH STABLE RENAL FUNCTION

- Output of Creatinine
   A) Males: O.P. = LBW (29.3 — 0.203 Age)
  - Females: O.P. = LBW (25.3 0.175 Age)
- Most Recent Serum Creatinine
   Average Output of Creatinine
   A.O.P. = O.P. [1 0.03 Cr]
- 4) Creatinine Clearance (CCI)

$$CCI = 100 \times A.O.P.$$

$$Cr \times 1440$$

ADAPTED FROM: MAWER, G.E. et al: Computer-Assisted Prescribing of Kanamycin for Patients with Renal Insuffiency. *The Lancet* 1:12-15, January 1, 1972.

Table 5

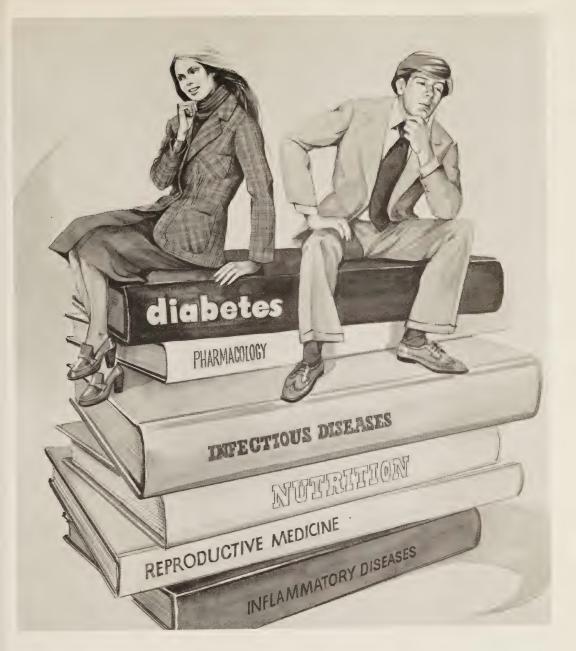
In my practice, a great deal of thought and effort enters into the treatment of Gram-negative bacillary infections with aminoglycosides. Because of this we have no difficulty in instituting therapy with these antibiotics.

I believe that with proper monitoring and dosage adjustments, any antimicrobial agent can be given with greater chance to avoid intrinsic toxicities and side effects. It has been shown that the nephrotoxicity associated with the aminoglycosides is associated with the concentrations achieved within the kidney itself. Tobramycin seems to be the aminoglycoside with the least inherent nephrotoxicity. If this turns out to be true, it may be due to the fact that less drug is sequestered in the kidneys. The use of this drug may be a special role in the treatment of sensitive infections in the elderly who already have impaired kidney function.

(continued on page 10)

SEX	LBW (Kg)	Cr (mg-%)	AGE	CCI (ml/min)
M	70	1.1	20	108
M	70	1.1	30	99
M	70	1.1	40	90
M	70	1.1	50	82
M	70	1.1	60	73
М	70	1.1	70	64
М	70	1.1	80	56

Table 6



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Speaking of aminoglycosides apart from renal function, research is now trying to produce aminoglycosides free of toxicities. Netilmicin appears to be a drug that is a giant step forward with regard to ototoxicity. If this turns out to be a fact, much use of this agent is possible for infections that require high concentrations in closed spaces such as the inner ear or meninges.

Knowledge of the toxicities of antimicrobials and the means of avoiding those toxicities are critical to the best antimicrobial care.

#### Age and Gastric Acidity

In Table 7 we see listed two extremes in the hydrochloric acid content of the stomach seen in many older people. Hypochlorhydria is a diminished amount of hydrochloric acid in the stomach and achlorhydria is simply an absence of hydrochloric acid in the stomach.

Whether or not some antimicrobial agents will produce a satisfactory therapeutic effect when given by mouth depends on the stability of the drug in acid and of pH of gastric juice. Age is one determinant of the hydrogen ion concentration of the stomach contents. The pH of the stomach contents reaches that of the adult at 3 years of age. The acidity of gastric juice falls with increasing age in both men and women. Hypochlorhydria occurs in the elderly at a rate ten times greater than in the young adult groups.

These conditions can be most significant in the therapy of infection in patients with drugs that are sensitive to the hydrochloric acid level in the body. Examples of these drugs are: penicillin, erythromycin, oxacillin, cloxacillin, dicloxacillin, and nafcillin.

Because decreased gastric acidity and achlorhydria are common in the elderly, the absorption of some orally administered antimicrobial agents is better in elderly persons that in younger ones. Studies reported that the quantities of penicillin detectable in the circulation after oral administration were higher and more sustained in patients with achlorhydria (4-6 hours) than in normal persons (2-4 hours).

Thus, the possibility exists that the administration of antibiotics by mouth will cure an infection is greatest in the older adult, especially if achlorhydria is present.

#### Age and Stomach Emptying Rate

Animal studies indicate that the aging process can change the number and properties of effector cells in the nervous system. Thus, physiological processes such as gastric emptying, under control of the nervous system may occur at a slower rate in the elderly.

The rate at which the stomach empties has a direct bearing on the amount of drug that is absorbed into the systemic circulation. There are many factors that influence the rate at which the stomach empties. In Table 8 we see a partial listing of these influences. Drugs such as anticholinergic agents, such as Robinul, Pathibamate, Librax, and even agents that possess anticholinergic activity such as Valium, Librium, and the phenothiazine antipsychotic agents such as chlorpromazine all effect a slower rate at which the stomach will empty. Narcotic analgesics and other analgesics such as aspirin also slow the rate at which the stomach empties. Mental states such as depression and meals that are high in fat and carbohydrate slow the emptying time. Also included is the slower rate of emptying that is present by virtue of the aging process. The rate at which the stomach empties is increased by such factors as an aggressive emotional state and drinking liquids which are close to body temperature. On initial perusal of the list, one can see that the elderly may have many of these influences at the same time and if their stomach does empty at a slower rate, the amount of drug reaching the systemic circulation may diminish or be absorbed over a longer period of time.

The absorption of weakly basic antibiotics such as erythromycin and tetracycline (tetracycline is more amphoteric) depend upon primarily the stomach emptying rate. Stomach emptying rate is especially critical for weak bases because they are not absorbed in the stomach whereas weak acids such as penicillin and sulfonamides, are absorbed, at least in part in the stomach. If the slower emptying rate were the case, there could be a delay or a decrease in the absorption of weak bases.

#### Age and Drug Absorption

Elderly patients can be expected to absorb drugs less consistently or more erratically than younger adults. There are not many studies looking particularly closely at this problem so specific guidelines regarding agerelated absorption problems do not exist.

#### **GASTRIC ACIDITY**

- 1) Hypochlorhydria
  - 2) Achlorhydria

#### STOMACH EMPTYING RATE

#### Slowed By: 1) DRUGS

- A) Anticholinergics
- B) Narcotic Analgesics
- C) Analgesics (e.g., Aspirin)
- **DEPRESSION**
- FATTY MEALS and CARBOHYDRATE MEALS
- AGING PROCESS

#### Increased By:

- AGGRESSIVE EMOTIONAL STATES
- HAVING TEMPERATURE CLOSE
- TO BODY TEMPERATURE

#### "LAW OF MASS ACTION"

Rate of a Chemical Reaction is Proportional to the Molecular Concentration of the Reacting Substances.

#### Table 9

The law of mass action as it is stated in Table 9 is an often overlooked principle in the absorption of antibiotics. Simply stated it means that the greater the amount that is presented for absorption the faster the drug is absorbed. It must be noted that it is the unionized portion of the drug that is absorbed across the intestinal mucosa. Drugs that exist in the gastrointestinal tract in their ionized form will not be absorbed to any great extent. In Table 10 we see some examples of drugs that are weak acids. Keeping in mind that the portion of the equation, HA, is the unionized portion, if a weak acid is presented to the stomach and the concentration of the

present. In this case, then, higher blood levels and faster absorption of these drugs is possible.

Table 12 lists common drugs that present with impaired absorption because of poor aqueous solubility.

Drugs that have poor aqueous solubility such as griseofulvin or ampicillin are those for which absorption is often impaired. Their absorption is normally limited by the dissolution rate in gastric fluid. With this slower absorption, the agent is present in the gastrointestinal tract for a longer period of time. Therefore, what may be an annoyance to a young adult (loose stools with ampicillin or tetracycline) can become a true therapeutic headache if these same drugs were to cause copious diarrhea in an elderly person. The increased side effects of these agents is due to the increased time they are present in the gastrointestinal tract. With all of this in mind, if decreased therapeutic effect or increased incidence of side effects is seen, absorption abnormalities should be considered.

#### **WEAK ACIDS**

(Penicillin, Sulfonamides, Barbituates, Phenylbutazone, Aspirin, Acetaminophen)

† HA + + A

† H+--- † HA (Unionized Portion)

# WEAK BASE (Conjugate Acid of Weak Base)

(Erythromycin, Tetracycline, Tricyclic Antidepressants, Amitriptyline, Diazepam, Pentazocine)

BH+==B + H+

† H+ → † BH+ (Ionized Portion)

N.B.: The Unionized species is more soluble in the cell membrance and, hence, diffuses more readily.

## DRUGS WITH POOR AQUEOUS SOLUBILITY

- 1) Griseofulvin
- 2) Ampicillin
- 3) Tolbutamide
- 4) Digoxin

Table 10

Table 11

Table 12

#### acid or the H+ is increased, the equation will be forced by the law of mass action to the left and HA or the unionized portion is formed. It is the unionized portion of the drug that is absorbed. With this in mind, it is conceivable then that some of the weak acid when administered and maintained in an unionized portion of the stomach will be absorbed directly through the stomach wall.

In Table 11 we consider the conjugate acid of the weak base and the examples of drugs that are weak bases. Once again, remember that it is the unionized portion of the drug that is absorbed systemically through the intestinal wall. If a drug such as erythromycin which is a weak base (indicated in the equation by B) is administered in an acidic medium, the equation by virtue of the law of mass action will be forced to the left and the ionized portion of the drug, that is BH+, is formed and the drug will be in its nonabsorbable form. One can see then that if a drug such as erythromycin or tetracycline which are weak bases is administered to an elderly person who is hypochlorhydric or achlorhydric, the drug will exist in its unionized form (that is, B). The H+ portion of the equation falls, the equation is forced to the right and a greater amount of unionized drug will be

#### Age and Hypersensitivity

The area of hypersensitivity reactions is one with which we are all familiar. There have been many times that we have asked a person whether or not they were allergic to penicillin. Hypersensitivity reactions to antibiotics (and all drugs in general) have been reported to be greater in number in the elderly than in the younger adult population. Even without documented evidence proving this statement, logic tells you it is a very real possibility because the longer a person lives the greater the possibility that exposure to one of these drugs will be made. The clinical implication of this increased potential for hypersensitivity reactions is very apparent. Elderly patients who are given antibiotics known to be associated with hypersensitivity reactions should be watched more closely.

#### Age and Metabolic Abnormalities

A disease common to many older patients as well as those classified as younger adults is diabetes. Two studies were undertaken to distinguish the various ways of dealing with intramuscular penicillin G in diabetic patients.

Table 13 compares the blood levels of penicillin after intramuscular administration to both normal and diabetic patients. Diabetes is a disease common in the elderly and can produce profound changes in the magnitude of the blood levels obtained and the time to obtain these blood levels in a diabetic patient.

#### CONTRAST OF BLOOD LEVELS OF PENICILLIN G AFTER I.M. ADMINISTRATION TO NORMAL AND DIABETIC PATIENTS

	Normal	Diabetic
Peak Blood Levels (mcg/ml)	8	5.4
Time to Peak (Hours)	1	2

Ref.: Weinstein, L. and Meade, R.H.: Absorption and excretion of Penicillin injected into muscles of patients with diabetes mellitus. *Nature* (London) 192:987, 1961.

Table 13

Adults with diabetes mellitus handled the intramuscular penicillin G in a manner different from that of the normal patients matched for age and sex. A single dose given on a units per kg basis produced peak blood levels that were different and that occurred at different times. Peak blood levels were reached in one hour in the controls and in two hours in patients with diabetes. The peak blood levels were higher (8 mcg/ml) in the controls than in the diabetic patients (5.4 mcg/ml).

These results suggest that when a penicillin or other antimicrobial agent is to be used in elderly diabetic patients and when high peak blood levels are going to be required, then intravenous administration should be employed if at all possible. This should also be done if an elderly patient fails to respond to an adequate intramuscular dose of an antibiotic.

#### Antibiotic Agents and Adverse Reactions in the Elderly

All antibiotics should be used with care when administered to the geriatric patient. Twenty percent of all adverse reactions to antibiotics occur in patients 65 years and older.

Care must be taken to realize that an elderly person will not respond to antimicrobial therapy as quickly as a younger person with a more active immune system. Remember that even if an organism is sensitive to an antibiotic, you can administer antibiotics in any dose and if the white blood cells are not working in that patient, the patient will not get well.

Toxic antibiotics that are excreted relatively un-

# Joint MPhA-MSHP Statement on Supportive Personnel

Adopted at the 1978 Annual Convention

- A. "MSHP-MPhA Joint Statement of Principles on Supportive Personnel"
  - The Pharmacist is responsible, legally and professionally, for the control of all drugs dispensed in the pharmacy and for the proper patient consultation on drug therapy. The development of expanded professional services by Pharmacists emphasizes the need for supportive personnel to assume many of the routine, nonjudgmental duties traditionally associated with the delivery of pharmaceutical services.
  - 2. The term "supportive personnel" is adopted as standard nomenclature to be used in referring collectively to all nonprofessional personnel. Those persons utilized in purely clerical activities, and a pharmacy intern/extern or student completing hours of experience toward completion of the Board of Pharmacy requirements are not considered supportive personnel.
  - Supportive personnel may be used in performing pharmacy tasks under the immediate personal supervision of a pharmacist who is present within the same work area.
  - Pharmaceutical products prepared by supportive personnel shall be certified for accuracy by a pharmacist prior to release for patient use.
  - 5. Written procedures for the use of supportive personnel shall be prepared by the pharmacist.
- B. The MPhA and MSHP shall jointly issue a set of guidelines concerning the training, credentialing and utilization of pharmacy supportive personnel.

changed by the kidney must be used cautiously in treating elderly patients because of their decreasing renal function.

Remembering that gastrointestinal changes in the elderly such as gastric pH and motility may alter response to antimicrobial therapy is an important consideration in the application of antibiotic therapy to elderly patients. Also, underlying diseases such as diabetes mellitus, may have a substantial influence on drug therapy especially concerning the route of administration.

The elderly patient presents a difficult therapeutic problem because of a compromised physiological system. Because of the great variation from one person to the next, the physiological changes we know about do not allow adequate prediction about response of an elderly patient to drug therapy.

Antibiotic therapy is just one area of the overall therapeutic picture in the geriatric patient that must be accomplished with great care, logic, and sensibility.

#### CE Quiz on page 17

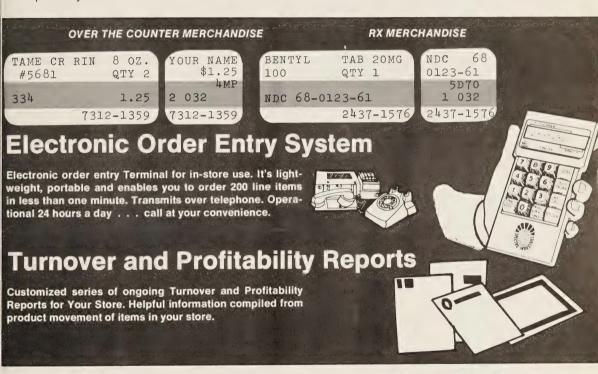
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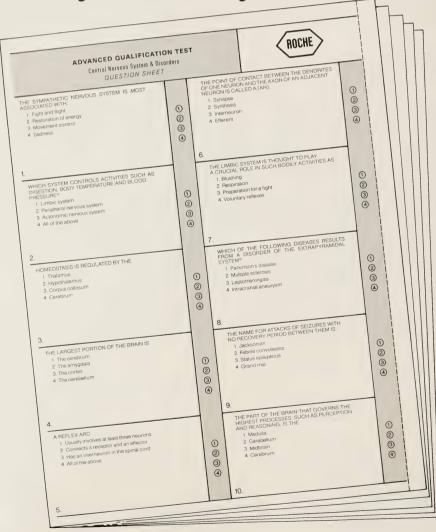
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13

# No. 4 in a series.

# Your Roche Representative has to answer some pretty tough questions.

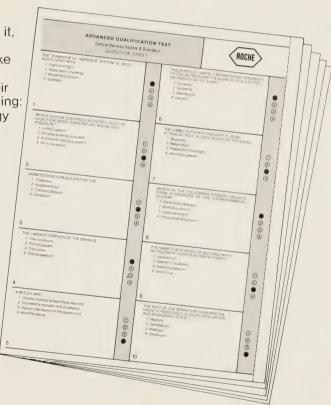
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# Drug Topics' Consumer Expenditure Study Shows Pharmacy Sales Up

While 1977 was not a spectacular year for drugstore sales, there were gains across a wide product front that pushed sales in nonprescription areas to a new high, according to Drug Topics' annual survey of consumer expenditures.

Covering 25 major departments and some 304 items sold in drugstores, Drug Topics' study disclosed that 239 of those items gained in sales volume over the previous year, while only 61 lost ground. The gains pushed total upfront sales to \$12.06 billion, a gain of 5.4%.

Comparing the drugstore share of market with the prior year, 69 item categories were down in share, only 52 were up; but in 175 item categories, drug outlets retained their share of market in spite of increasing pressures from nondrugstore mass merchandising of traditional drugstore items.

The three leading categories in drugstore sales volume were: packaged medications, photographic equipment and supplies, and tobacco products and smokers' accessories.

Packaged medications, traditionally second only to prescription sales in volume, accounted for slightly more than 13% of total drugstore sales last year. Cough and cold items, the mainstay of packaged medications, had a small volume increase and climbed three percentage points (to 65%) in drugstore share of market. The second biggest contributor to the packaged medication category, internal analgesics, grew at a faster rate than cough and cold items, but lost a percentage point in the drugstore share of market. Vitamins, the third largest sales contributor to the packaged medication category, grew at better than an 8% rate in drugstores. Contraceptives, with an 18.6% gain in sales volume, acne preparations, which rose 31%, and medicated soap, up better than 28%, were star performers within the category.

Photographic equipment and supplies provide the largest drugstore sales volume after packaged medications. The category had a good sales gain of 11.5% over 1976 and held steady in drugstore share of market at 29%.

Tobacco products and smokers' accessories, the third biggest sales-maker in drugstores at 5.8%, contri-

buted nearly \$1.2 billion in sales and held its share of market, with more than \$937 million attributed to cigarette sales.

Another mainstay of sales, hair products, was responsible for nearly 4% of drugstore sales and increased its drugstore share of market last year, now about one-third of the total market. Hair preparations continue to dominate the category, with shampoo, hair tints and dyes strongly boosting sales volume.

Cosmetics had a good year, increasing 8% in sales volume and moving up two percentage points in drugstore share of market. Fragrance products remained on dead center as far as sales volume growth in drugstores and gained only slightly in nondrugstores and in total market.

Personal cleanliness items gained 5% in drugstore volume and 1% in drugstore share of market. External personal deodorants is the primary volume producer in the category, with big gains made by roll-ons, up nearly 45%, and sticks, almost 43%. Also in the personal care area, shaving product sales in drugstores increased at a slightly faster rate than those in nondrugstores. Aftershave lotion and men's cologne, the top sales producers, were up 11.4% and 5.1% respectively. Cologne share of market rose to 44%, while after-shaves held their own at 40%.

Other products showing sales gains were magazines, newspapers, and paperbacks, up 9.8%, topping gains in nondrugstores and in the total market; stationery — writing implements, greeting cards, and paper and supplies — was up 5.3%, with greeting cards the big volume producer.

Sundries didn't rise as much in drugstores as in nondrugstores, but retained their drugstore share of market. Toys were the biggest sale item in the group, climbing 6.9% in drugstore volume, less than nondrugstore outlets. Watches had a smaller gain — 2.1%.

In confectionery, chewing gum was up nearly 15% in drugstore sales, while bar candy, a far larger money maker, was up more than 9%.

# **Self Evaluation Quiz**

# Antibiotic Therapy in Geriatrics

by

Thomas C. Majerus, Pharm.D. (May be more than one correct answer)

- 1. In which form must a drug exist for absorption across cell membrances to occur?
  - a. Unionized
  - b. Ionized
  - c. Amphoteric
  - d. Radicalized
- 2. On review of a patient profile before dispensing an antibiotic, which of the following would indicate to you a slower than normal rate of stomach emptying?
  - a. Chlorpromazine 50 mg q.i.d. concurrently
  - b. Glycopyrrolate 1 mg q6h concurrently
  - c. Patient's age = 32
  - d. Patient's age = 62
- 3. The pH of the gastric juice:
  - a. is greater in a person 60 years old than one 20 years old.
  - b. is less is a person 60 years old than one 20 years of age.
  - c. is greater in a person 2 years of age than one 20 years of age
  - d. is less in a person 2 years of age than one 20 years of age.
- 4. Which of the following statements is (are) true?
  - a. Geriatric patients are more susceptible to infections with normal microbial flora than are younger patients.
  - b. Even though renal function decreases with advancing age, a serum creatinine that is in the "normal" range means that a geriatric patient will have 100% kidney function.
  - Because of the possibility of achlorhydria in the elderly, penicillins given orally may be degraded to a lesser extent in the stomach.
  - d. Drugs that are weak acids exist in the unionized state in acidic media.

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- 5. Creatinine clearance is useful:
  - a. to evaluate kidney function.
  - b. When dosing antibiotics excreted renally.
  - c. because it rises when a person is infected.
  - d. because as creatinine clearance falls, improvement is seen in the patient.
- 6. A 55 year old male is 5'9" tall, medium frame and a serum creatinine of 1.3 mg/dl. What is his creatinine clearance?
  - a. 65.9 ml/min
  - b. 53.1 ml/min
  - c. 63.3 ml/min d. 54.7 ml/min
  - Elderly nationts who are o
- Elderly patients who are given antibiotics known to be associated with hypersensitivity reactions should be watched more closely.

True or False

 It can be stated that absorption of intramuscular antibiotics by diabetic patients occurs as readily as in nondiabetic patients.

True or False

- 9. Which of the following antibiotics is (are) excreted renally?
  - a. Doxycycline
  - b. Penicillin
  - c. Methicillin
  - d. Nafcillin
- Because erythromycin is a weak base, it will exist in the acidic gastric contents in an unionized form and be partially absorbed through the stomach wail.

True or False

#### **Instructions for Self Evaluation Quiz**

Since many states now have mandatory continuing education requirements for pharmacists and it is anticipated that Maryland will soon pass a similar law, the MPhA is providing this special quiz for members so that they may receive the most benefit from continuing education articles appearing in the MARYLAND PHARMACIST.

The MPhA staff will grade and record this and any future quizzes and keep them in a personal file for each pharmacist. A grade of 90% or above is required in order to receive a passing mark. If you fail the quiz, it will be returned to you and you may resubmit the quiz only once with corrections made in a different color ink than was used the first time.

The MPhA will correspond with any state where a member is registered that requires continuing education participation to verify that member's participation in this program.

When submitting quizzes, please observe the following:

1) Paste your current mailing label to the quiz before sending it

to the MPhA office. Use the boxed-in space provided on the quiz front. Please use the label from *this* copy of the MARY-LAND PHARMACIST only. This will serve as a membership verification.

- 2) Use business-size envelopes when mailing to the office.
- Please submit this quiz and others as soon as possible after receipt.
- 4) Please use appropriate amount of postage.
- Correct Quiz answers are available upon request from the MPhA office; call or send a self-addressed, stamped envelope with the quiz.
- 6) Remember this is a free service for members of the MPhA

The MPhA will keep records for each participant and will issue a certificate annually showing the number of quizzes which have been successfully completed. Watch for other continuing education articles and quizzes in future issues of the MARYLAND PHARMACIST.



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# Recollections

A Medical Scientist Remembers

by John C. Krantz, Jr., Ph.D., F.A.C.C.



#### **Book Review**

by
William J. Kinnard, Jr., Dean
University of Maryland, School of Pharmacy

I didn't have the fortune to meet John Krantz until after my arrival here in Maryland in 1968, but his fame and reputation had reached me through various sources before that time. In 1955 I arrived at Purdue to work on my Doctorate and was fortunate to have as my major professor Dr. C. Jelleff Carr, who also just arrived at Purdue coming from Dr. Krantz' faculty team here at Maryland. I had the opportunity at that time to read "The Art of Eloquence" the book that John Krantz had coauthored with Governor McKeldin. That gave me my first glimpse of the multiple talents of this Marylander.

Subsequently, we used the classic pharmacologic text written by Drs. Krantz and Carr at the University of Pittsburgh. The relevance of its content made it a very effective book for our use.

John Krantz is an atypical person because of his many facets of interest. He's a pharmacist, a pharmacologist, a sailor, a scholar and many other things; but above all a gentleman. His autobiography reflects all of these characteristics as he talks about the highs and lows of his life. Certainly, his life was replete with highs and very few lows. although in the latter case his venture as an author was not too successful. He talks about his early childhood that revolved around his father's pharmacy and moved up through a number of careers until he reaches the present — a period of retirement in name only.

The book is interesting and something that is light reading for a lovely summer evening on the porch or a

# **University Library Offers Resource Help**

The Health Sciences Library of the University of Maryland, in addition to pharmacy, covers the subject areas of medicine, dentistry, nursing, and social work. The library ranks among the top ten health sciences libraries in the United States with over 210,000 volumes and over 3200 periodical subscriptions.

If you should need assistance in your search for information, various services are available.

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The CRABS (Computerized Bibliographic and Reference Services) Office can provide you with bibliographies tailored to your individual request for a nominal fee. The library has access to over 30 data bases covering the subjects of medicine, pharmacy, biology, chemistry, business, and many other fields. If you would like more information about this service, call 528-7373, Monday-Friday, 9 a.m.-5 p.m.

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The library is open to all health professionals for in-library use of material upon presentation of professional identification. Members of the University of Maryland Alumni Association are eligible to borrow material. For additional information concerning loan policies, call 528-7995.

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cold winter around the fire. This is especially true for those people who have known John and will be interested in hearing his view of many of the things that happened during his times as a faculty member in the Schools of Pharmacy and Medicine at the University of Maryland as well as his other efforts — vocational or avocational.

My disappointment with the book is a general one. I'm sorry that he didn't serve more as a chronologer of the times through which he passed. There were major changes at the University of Maryland at Baltimore as it evolved and grew through the 30's, 40's and 50's. It was also a time when research in Pharmacology moved from the days of rather simple instrumentation and scientific approach of John Jacob Abel to the more complex work that is seen today. A review of those changes and a philosophical summation of the changes that occurred would have been very useful, especially as focused through the eloquence of John Krantz' words.

William J. Kinnard, Jr., Ph.D.

Paul Reznek, the 1978-79 Honorary President of the MPhA, received his award at the Convention Banquet from President, Richard D. Parker.



1977-78 Ladies Auxiliary President, Bea Freidman, addresses the annual Banquet. The Auxiliary celebrated its 25th anniversary at the Convention.

# 1978 MPh Ocea Marylan

Pictures courtesy Paramount Photo Service



George Maggio, vocal past president of the Pennsylvania Pharmaceutical Association and Chairman of the American College of Apothecaries' Third Party Committee, delivered the Simon Solomon Lecture.



Mary Ann Parker received the "Pharmacists Mate Award" from Geigy Representative William Brown.



A standing room only crowd heard the continuing education presentation on Common Gynecological Problems sponsored by Lederle.



Anne Lane (left) and Annabelle Hecht from the Federal Food and Drug Administration represented one of several exhibitors at the annual Convention.

# onvention ty emories

Pictures courtesy Paramount Photo Service



Henry Seidman and Friends are caught boarding the Berlin, Maryland fire truck for a quick tour of the city following the crab feast, but before the square dancing. Over 300 persons gathered in the fire house for the event.



Acting Governor Blair Lee III dropped in on a Convention meeting. His opponent for the Fall Primary, Baltimore County Executive Ted Venetoulis participated in the Crab Feast.



In-coming President Stanley Yaffe presents the Association's Past President's Award to Richard Parker.



1977-78 MPhA President Richard Parker receives the Past President's Award from Squibb representative



Once again, members of the Travelers Auxiliary of the MPhA manned the registration desk and provided other assistance in the course of the Convention.



Stanley Yaffe, 1978-79 MPhA President, is pictured with his family at the annual Banquet at the Carousel Hotel.



Henry G. Seidman (center), of the University of Maryland's School of Pharmacy in Baltimore, receives the A. H. Robins "Bowl of Hygeia" Award – for outstanding community service by a pharmacist – from James W. Owings, Sr., manager of the Capital Division of A. H. Robins Company. Looking on at left is Richard D. Parker of Glenwood, President of the Maryland Pharmaceutical Association.



In a surprise announcement, Melvin Rubin (left), Chairman of the MPhA Board of Trustees, received a special presentation from President Richard Parker at the Banguet.

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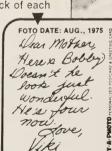
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### Resolutions adopted at Convention House of Delegates meeting

#### Resolution one

WHEREAS, the officers, delegates and guests of the Maryland Pharmaceutical Association are deeply thankful for the kindness, cooperation, and generosity extended them by Radio Station WCAO and FM Station WXYV.

THEREFORE, BE IT RESOLVED that the officers and delegates of the Maryland Pharmaceutical Association extend their deep appreciation and sincere thanks to Mr. Joseph Cahill, Manager of Radio Station WCAO and FM Station WXYV by presenting him with a suitable plaque as a token of gratitude.

#### Resolution two

WHEREAS the members of Congress of the United States serve as our chosen representatives, and

WHEREAS they should receive the ultimate in health care services available to the population and,

WHEREAS the Congress has been denied this right by the Surgeon General through his refusal to appoint a Pharmacist to be responsible for the prescription drug needs and pharmaceutical services including professional counseling.

THEREFORE, BE IT RESOLVED, by the Maryland Pharmaceutical Association in Convention assembled, that a request be conveyed to the Vice President of the United States as the presiding officer over the Senate and the Speaker of the House as the presiding officer over that body, to ensure that a full time pharmacist shall personally supervise and provide pharmaceutical services in the Capital Pharmacy.

#### Resolution three

**BE IT RESOLVED** by the Maryland Pharmaceutical Association, in Convention assembled that a copy of the letter from Pharmacist M. Neal Jacobs concerning drug control inspections be sent to the American Pharmaceutical Association and the National Association of Retail Druggists with a request that they work at the national level to make changes as appropriate; and be it further

**RESOLVED** that a copy of this letter be sent to the Drug Enforcement Administration with a request that they give consideration to appropriate regulation changes; and be it further

RESOLVED that the Maryland Pharmaceutical Association arrange a meeting with state and federal officials to request more appropriate interpretation of their regulations. This meeting should be held concurrently to overcome conflicts in interpretations between state and federal agencies, and be it further

RESOLVED that legal counsel for the Maryland Pharmaceutical Association be requested to investigate privacy laws and how recent trends in inspections and auditing has impacted upon these laws.

Dear Mr. Banta:

On April 5, 1978, my pharmacy was inspected by a Drug Inspector from the Division of Drug Control, State of Maryland. On April 18, 1978, I was directed by Mr. Charles Tregoe, Chief of the aforementioned division to appear in Baltimore for an informal hearing reference the following pharmacy inspection reports:

#6 — "CDS not rewritten when practitioner wishes to continue original prescription within 6 months or 5 refills." This requirement is clearly arbitrary and capricious with no substantive regulatory purpose or benefit to the health and welfare of the citizens of Maryland. On the other hand, the advantages to continue refilling the original prescription until either 5 refills or 6 months has been reached is good pharmacy practice because it provides a refill history for the pharmacist, prevents errors in transcribing and removes an administrative burden from the pharmacist's duties without any loss of regulatory audit capabilities. It is therefore unreasonable and thus unlawful for either the State of Maryland or the Federal agency to demand compliance.

#11—"Dating of Schedule 3, 4, and 5 invoices." All of the invoices are received with a date provided by the shipper. The only time an exact date of receipt would be significant is on an audit day or inventory day so that the CDS received for that particular day would be accountable.

#12—"CDS invoices are not readily available." The CDS invoices are not kept on the premises because of a history of numerous burglaries at my pharmacy. The invoices were available for the audit on April 5, 1978, within 2 hours of the request. I believe that the spirit and intent of the regulation is met in 2 hours. Furthermore, it is not unreasonable to have the State notify the pharmacist prior to the time of their inspection, and/or audit.

#13 — "Third copy of Federal order form properly filled in." I am presently stapling the duplicate, computerized, dated invoice to the Federal order form. In addition, I have a monthly computer print-out supplied by my wholesaler, documenting all controlled drugs purchased for each month. It is absolutely unreasonable that anyone of the aforementioned documents is not sufficient for a regulatory agency's auditing purposes.

#14 — "Patient address on CDS prescription." All patient's addresses are available for regulatory purposes on their patient-record cards. The authenticity of any address is uncertain and especially if the patient is attempting to fill an unlawful prescription. The surveillance by the State of the personal prescriptions of private citizens who have committed no crime, but have been given a controlled drug substance by a licensed physician is a questionable practice. Therefore, considering the privacy issues, and the lack of credibility of any name and address, I believe that the State should acknowledge the patient-record card as sufficient to meet any regulatory requirement which demands the name and address of patients.

#22 — "Outdated products offered for sale." The charge describing outdated prescription items offered for sale is an outrageous and libelous allegation. There are no facts to substantiate such a charge. The State's assumption that the mere possession on the shelf of the prescription department of an outdated medication is tantamount to dispensing such an outdated medication is a step no reasoning person would conclude.

During the inspection of April 5, 1978, an audit was conducted by the inspector (Sachs) of Quaalude and Dexamyl #2. The audit confirmed my inventory figures of almost 11 months ago. If my CDS invoices and record keeping procedures were deficient as the State has indicated, then how did the drug inspector successfully accomplish an audit of Class 2 drugs? The

regulations are promulgated by bureaucrats with an attitude that behind every prescription department lurks a thief, a criminal who must be shackled in his thinking and conduct lest the public be deluged with an avalanche of illegal drugs. The regulations so zealously enforced are not designed for the protection. of the health and welfare of the citizens of Maryland, neither are they solely designed to effect accountability. Instead they are a contrived set of arbitrary and capricious rules by design, in the words of Irv Myers "to be troublesome." It is foreign to our system of government that a few bureaucrats with twisted and narrow views, tainted with their own lack of personal esteem or overwhelmed with their own sense of importance and prejudices can enforce those views upon an entire profession. Nevertheless, this has happened, and I believe that the time has come for pharmacists to break the chains that intimidate, harass, and degrade us. We must be free to practice our profession without the presence of the police state mentality that pervades our present practice. That freedom can and must be found in the Courts. No better investment could be made for the future health of pharmacy than to confront Section 6, 11, 12, 13, 14, and 22 of the Tregoe-Myers Report Card in the Courts. This Association should advise Secretary Neil Solomon, the Governor of Maryland, and the Attorney General's office, and the Federal Drug Enforcement Administration of our decision to take legal actions in the Courts against what we believe are arbitrary and unreasonable rules that unfairly interfere with the legitimate practice of pharmacy.

M. Neal Jacobs, Registered Pharmacist

#### Resolution four

**WHEREAS** the patient has the right of freedom of choice in selecting the source of pharmaceutical services and.

**WHEREAS** regulation and control procedures are necessary for the protection and safety of the public,

**BE IT RESOLVED** that the Maryland Pharmaceutical Association support legislation or regulation changes permitting the transfer of prescription information between pharmacists for the purpose of refilling prescriptions, and be it further

**RESOLVED** that the Maryland Pharmaceutical Association support the establishment of proper controls over this procedure to prevent unauthorized use of prescription medications.

#### Resolution five

**RESOLVED,** by the Maryland Pharmaceutical Association in Convention assembled that a letter of thanks and appreciation be sent to 1978 Convention Committee Chairman, Ronald Lubman for the outstanding work he and his Committee performed in conjunction with the 1978 Annual Convention of the Maryland Pharmaceutical Association.

#### Resolution six

**RESOLVED** by the Maryland Pharmaceutical Association in Convention assembled that the Association, in conjunction with legal counsel, set up and distribute necessary guidelines for pharmacists and pharmacies to follow when audited by any third party provider.

#### Classified Ads



#### Classified ads are a complimentary service for members.

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Available free to members, notification form to be given to patient under drug product selection law. Call Sharon (301) 727-0746.

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August 13 — AZO Fraternity Crab Feast

August 20 — Eastern Pharm. Society Crab Feast

Sept. 10 — PG/Mont. Co. Pharm. Meeting

Sept. 10 — Upper Bay Assn. Crab Feast

Sept. 17-21 — NARD Convention, New Orleans

Sept. 17 — MPhA Benefit Dinner Theatre, Colony 7

Oct. 5 - Balassone Memorial Lecture

Oct. 16-24 — Monte Carlo Trip

Oct. 26 - MPhA Fall Regional

Oct. 29 — Alumni Association Oyster and Bull Roast

Oct. 29 — PG/Mont. Co. Installation Banquet

Jan. 13 — Winter Trip to St. Martin

Feb. 11 - BMPA Annual Banquet

AUGUST, 1978

## Liability Protection (It comes with every tablet you dispense)

A recent article on pharmacy law stated that "it is not unlikely that pharmacists substituting therapeutically or bioequivalent drugs for those prescribed will face increasing confrontation in the courts on the issue of their liability for unanticipated or ad-

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It should be reassuring to know, therefore, that McNeil Laboratories stands

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> copy, you might like to send for one.)

> With the many problems facing the pharmacist today, why risk unnecessary liability problems.

\*From a special report reprinted from U.S. Pharmacist 2(4):18-23, 1977: "Pharmacy Law," by Michael R. Sonnenreich, J.D.



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## MSHP Williamsburg Annual Meeting



Gavel Exchange: David R. Chason (left) accepts gavel as incoming President. Presenting gavel is Arthur N. Riley, outgoing President.



Special Society Citation: Thomas King (left), Regional Manager, The Upjohn Company, accepts a Special Citation from MSHP for his support and promotion of Continuing Education for the Institutional Pharmacists of Maryland.



New Officers for 1978-79 year are (I. to r.): Richard Rumrill, Board of Directors; David Arrington, Treasurer; Karen Demsky, Secretary; David Chason, President and Ronald Telak, President-Elect.



Presidential Address: Sister M. Gonzalez Duffy, President, American Society of Hospital Pharmacists delivers banquet address to the more than 230 attendees at the 13th Annual Installation Banquet.



Pfizer Award: Steven Cohen (center) accepts the Hospital Pharmacists of the Year Award from Arthur N. Riley, President, MSHP and Patrick Birmingham, Director, Pharmacy Services, Good Samaritan Hospital. This Award is presented annually for outstanding contributions in the field of Hospital Pharmacy.



Geigy Achievement Award: Richard Plotkin (left) of Geigy Pharmaceuticals presents the Annual Achievement Award to Arthur N. Riley for achievement on behalf of Hospital Pharmacy during 1977-78.

# It's Triple X by a knockout

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## THE REVEREND EDWARD STONE AND ASPIRIN

John C. Krantz, Jr., Ph.D.

Professor Emeritus Department of Pharmacology University of Maryland School of Medicine

Hippocrates, the father of medicine, on the island of Cos about 2,400 years ago limited his armamentarium of drugs to mainly cathartics and sedatives. He was, however, aware of the medicinal virtues of the bark of the willow tree. He recommended the use of the juice of the willow tree as a diuretic. It appears that he was unaware of its antipyretic and analgesic properties. Various portions of the willow tree found their way into the herbals and were used as home remedies during the Middle Ages. The striking activity of the bark of the willow tree is that of antipyresis. This medicinal virtue was not discovered until the middle of the eighteenth century.

In 1763 the Reverend Edward Stone wrote to the president of the Royal Society and described his experiences with the use of the willow bark in the treatment of fever. It was bitter and reduced fever; he therefore compared it to the Peruvian bark (Cinchona) that contains quinine. He wrote as follows:

"As this tree delights in moist or wet soil, where agues usually abound, the general maxim, that many natural maladies carry their cures along with them, or that their remedies lie not far from their causes, was very apposit to this case, and I could not help applying it; and this might be intention of Providence here. I must own had some little weight with me."

Stone used the dried powdered bark and gave 20 to 60 grains every four hours. He treated 50 cases of "Ague and intermittent disorders". He occasionally used Peruvian bark with the willow bark in some of the cases. He reported that the results were uniformly satisfactory. Indeed, following Stone's report, some physicians believed that the willow bark had the same virtues possessed by the more expensive Peruvian bark and this instituted a more abundant use of the willow bark.

In 1826 salicin, a glucoside from the willow bark, was isolated and found to be the active principle. In 1838 Piria prepared salicylic acid by the hydrolysis of salicin.

The present era of salicylic therapy begins in 1874 when Kolbe and Lautemann synthesized salicylic acid. The acid is a white crystalline powder that is sparingly soluble in water and is an escharotic to the skin and mucous membranes. It exhibits antiseptic properties and was extensively used as a preservative for meat and milk. The sodium salt of the acid enjoys only mild antiseptic properties but is far less erosive to the skin and mucous membranes. It was employed as an analgesic and antipyretic.

Soon sodium salicylate became the drug of choice in the treatment of rheumatic disease and fever. The Bayer Chemical Works in Elberfeld, Germany was interested in preparing derivatives of salicylic acid. Accordingly Von Gerhardt synthesized acetylsalicylic (Aspirin) in 1853. Salicylic acid was called spirasaure as it was obtained from the *Spiraea* family and saure is the German word for acid. Aspirin contains the acetyl group, hence the name *aspirin*. The drug lay fallow on the shelf of Bayer Laboratories until the turn of the century.

One of the chemists of the Bayer organization named Felix Hoffman, whose father suffered with rheumatism, and like many patients, did not tolerate well the analgesic sodium salicylate prescribed for him by his physician. He prevailed upon his son to obtain for him another drug that would likely be better tolerated and provide him with the relief of pain. Felix Hoffman took aspirin from the shelf and gave it dose-wise to his father. It excelled sodium salicylate in its analgesic activity and was well tolerated. Soon the medical profession became aware of the advantages of aspirin over sodium salicylate. Wolgemut in 1899 and also Dresser in the same year described their use of the drug.

The widespread use of aspirin as an analgesic increased with unusual rapidity. The relief of pain evoked by aspirin appears to be due to its capacity to block the pain impulses passing over the spinal nerves, not permitting them to reach the sensory area of the brain, and hence not interpreted by the individual as pain. Therefore euphoria and addiction is not developed even in prolonged use of the drug.

Aspirin has had many competitors but not any has achieved the success as an analgesic, as has aspirin, with minimum side effects. Among the competitors for the place of aspirin as a unique analgesic are the following: acetanilid, phenacetin, aminopyrine and acetamol. Each of these agents exhibit side effects that are undesirable and do not vie with aspirin for supremacy in the category of a home analgesic remedy.

The rise in the use of aspirin is indicated by the enormous consumption of the drug, estimated at 25 tons daily. The only side effect of aspirin is gastrointestinal discomfort and/or bleeding. This is estimated to occur in 0.015 percent of the large users of the drug. This side effect is obviated by taking the aspirin buffered and with much water.

The introduction of willow bark and subsequently salicylates, including aspirin, into medicine by the Reverend Edward Stone reminds one of the words of Emerson writing of the hand that rounded St. Peter's Dome:

"The conscious stone to beauty grew
He builded greater than he knew."



#### Gerry Hietala, Abbott research pharmacist, on flavoring:

"One 'yuck' from any of these panel members and it's back to the drawing board. This is the final, most critical test for flavoring in our suspensions. No matter how much effort goes into the flavoring system of a pediatric drug, this is the bottom line. Kids simply won't take a bad-tasting medicine.

There are two basic objectives in flavoring a suspension; first, naturally, you want to mask the drug taste. Erythromycin is a prime example. It's bitter. Second, you want to maximize flavor stability. Over a period of time even insoluable drugs will hydrolyze to a limited extent. The flavoring must be able to cover the increased bitterness to maintain palatability of the suspension.

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good taste . . . when the product is out in the field.

Quality is built into our product through a sophisticated system of flavor assessment. We utilize statistical preference testing in addition to the flavor profile method. These help us to arrive at a top quality taste and assure that it will be maintained in production. The result is a goodtasting product with maximum stability . . . medicine a sick kid is going to take for ten days without a single 'yuck'."



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M. pneumoniae – For respiratory infections due to this organism.

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Treponema pallidum—As an alternate treatment in patients allergic to penicillin. C. diphtheriae and C. minutissimum—As an adjunct to antitoxin. In the treatment of erythrasma.

Entamoeba histolytica—In the treatment of intestinal amebiasis.

L. monocytogenes—Infections due to this organism.

Establish susceptibility of pathogens to erythromycin, particularly when *S. aureus* is isolated.

#### **Contraindications:**

Known hypersensitivity to erythromycin.

#### Warnings:

Safety for use in pregnancy has not been established.

#### **Precautions:**

Exercise caution in administering to patients with impaired hepatic function. During prolonged or repeated therapy, there is a possibility of overgrowth of nonsusceptible bacteria or fungi. Surgical procedures should be performed when indicated.

#### **Adverse Reactions:**

Dose-related abdominal cramping and discomfort. Nausea, vomiting, and diarrhea infrequently occur. Mild allergic reactions such as urticaria and other skin rashes may occur. Serious allergic reactions, including anaphylaxis, have been reported.

#### **LETTERS**



MASSACHUSETTS COLLEGE OF PHARMACY

Hampden Campus

July 7, 1978

To The Editor The Maryland Pharmacist 650 W. Lombard Street Baltimore, Md. 21201

Dear Sir:

The article "Clinical Use of Tricyclic Antidepressants" by Bennett, J.A. is excellent. I have two comments:

- 1) On page 6 discussing plasma levels: this should read . . . "plasma levels of 50 to 200 ng per ml" . . . ng (nanogram) not mg (milligram). This could be very confusing for anyone attempting to monitor plasma levels.
- 2) Articles of this nature should be referenced. As example: who is Coyle? and where did he publish his data?: triiodothyronine use with tricyclics. This should be referenced.

All in all a good article. Keep up the good work.

Sincerely.

to Joan

M. E. Hoar Assistant Professor of Pharmacy

P.S. The quiz is a good idea.



STATE OF MARYLAND EXECUTIVE DEPARTMENT ANNAPOLIS MARYLAND 21404

July 6, 1978

Mr. David A. Banta Executive Director Maryland Pharmaceutical Association 650 West Lombard Street Baltimore, Md. 21201

Dear Mr. Banta:

I've just written a note to Dr. Stanley Yaffe telling him how much I enjoyed dropping by the 96th annual convention of the Maryland Pharmaceutical Association on June 19. I wanted to drop a companion note of thanks to you for having been instrumental in arranging that visit.

I hope the balance of your convention was quite pleasant and productive.

With my best regards.

Blan her in

Blair Lee III Acting Governor

#### ABBOTT

**Pharmaceutical Products Division** 

David W. Kruger

Abbott Laboratories
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Mr. David A. Banta Executive Director

Maryland Pharmaceutical Association

650 West Lombard Street Baltimore, Md. 21201

Dear Mr. Banta:

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This program was developed by The Massachusetts College of Pharmacy and consists of three booklets, each containing two articles on various aspects of Pediatric Drug Therapy. A self-assessment quiz is enclosed with each article. Continuing Education Credit has been applied for in the 14 states that currently require mandatory continuing education for relicensure.

The Pediatric Series is being distributed on a bi-monthly basis through our Professional Medical Representatives only in those states that require mandatory continuing education for pharmacy relicensure. Since your state does not require mandatory continuing education, copies of the Pediatric Series can be requested by writing to:

Mr. David W. Kruger, Manager Trade Relations, D-355 Abbott Laboratories North Chicago, Illinois 60064

We sincerely appreciate your effort in notifying the pharmacists in your state of the availability of this exciting new Continuing Education Program.

Sincerely.

David W. Kruger

David W. Kruger

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THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association

SEPTEMBER, 1978 VOL. 54 NO. 9



**Annual Report, Board of Pharmacy** 

- Paul Freiman, Secretary

1978 Membership Roster

**Drug Abuse Directory** 

- Compiled by Ira Fedder

1978 Fall Regional Thursday, Oct. 26th Holiday Inn at BWI Airport

#### THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET BALTIMORE MARYLAND 21201 TELEPHONE 301/727-0746



SEPTEMBER 1978

VOL. 54

NO. 9

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Change of address may be made by sending old address (as it appears on your journal) and new address with zip code number. Allow four weeks for changeover. APhA members — please include APhA number.

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DAVID A. BANTA, Editor SHARON SPIES, Assistant Editor ABRIAN BLOOM, Photographer

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#### **Inspections and the Rights of Pharmacists**

Few pharmacists would deny the inherent right of the state to regulate certain potentially abusable areas of Pharmacy in order to protect the safety, health and welfare of the citizens of Maryland. By judiciously exercising the police power of the state, we establish order in our society; and order is the hallmark of modern civilization.

There are times, however, when this power is not always judiciously exercised. Given the mass of rules and regulations which pharmacists must abide by, it is often very easy for any given inspector or auditor to find minor violations on any given inspection; no matter how meticulous and conscientious the pharmacist may be.

At some point in the process, these inspections cross over the line of insuring compliance with common sense rules into the area of nit-picking harrassment. In these cases it is difficult for us to determine how these inspections help to protect the citizens of this state as they were originally intended. Instead, they place the State in an adversary position with practicing pharmacists. This breeds mistrust of the State's motives. Instead of helping us comply with the myriad rules and regulations, these inspections lower the pharmacist's esteem and sense of self-worth. This process comes into direct conflict with the pharmacist's perception of the practice of the profession. Pharmacists are made to feel they are engaging in borderline criminal activity when minor infractions of the regulations are detected.

Obviously, the state has the right, and should watch over the practice of pharmacy. Flagrant violators of the law must be made to right their ways. But, some rules appear to be enforced for their own sake.

I am not sure what the ultimate answer to this problem is. However, we must strike a balance that preserves our professional integrity as pharmacists while allowing for common sense regulation for an orderly society.

Along Joy John

#### ANNUAL REPORT

OF THE

#### MARYLAND BOARD OF PHARMACY

1977 1978

(delivered at the 1978 MPhA convention)

In compliance with the provisions as set forth in Section 258 of Article 43 of the Annotated Code of Maryland, this report is submitted to the Honorable Blair Lee, III, Acting Governor of Maryland and to the Maryland Pharmaceutical Association. This is the seventy-fifth report to the Governor and the sixty-fifth report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the fiscal year ending June 30, 1978. This report is also being submitted to the Secretary of Health and Mental Hygiene, the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records, and the State Library.

An Annual Report was not submitted for 1976-77 due to the fact the Board has had numerous difficulties regarding secretarial assistance and the figures and necessary information were not compiled.

#### PERSONNEL

During the year the Board held sixteen meetings, six of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for registration of pharmacists.

There have been numerous changes relative to the composition of the Board and elected officers.

Mr. Morris R. Yaffe's term expired effective April 30, 1976 and Mr. Bernard Lachman was appointed effective May 1, 1976.

In accordance with H.B. 596, effective July 1, 1976, the Board was to consist of seven Commissioners, a licensed pharmacist and a consumer. Mr. Leonard J. DeMino, pharmacist, and Ms. Estelle G. Cohen, consumer, were appointed to the Board.

Mr. I. Earl Kerpelman's term expired effective April 30, 1977 and Mr. Paul Freiman was appointed to the Board effective May 1, 1977.

Mr. C. H. Tregoe's term expired effective April 30, 1978 and at this date a successor has not yet been appointed.

Mr. C. H. Tregoe resigned his position as Secretary-Treasurer effective January 1, 1976. This was explained that the Director of the Environmental Health Administration had informed him, in his opinion, there was a conflict as serving both as the Chief of the Division of Drug Control and Secretary-Treasurer of the Maryland Board of Pharmacy. Mr. Robert E. Snyder assumed the responsibility of Secretary-Treasurer. Effective August 10, 1977 Mr. Snyder resigned as the Secretary-Treasurer

and no one was elected to assume the responsibility. At the April 19, 1978 meeting of the Board, it was agreed Mr. Paul Freiman would accept the position of Secretary-Treasurer on a trial basis. Mr. Ralph T. Quarles is President of the Board and Mr. Morris R. Yaffe is Honorary President.

The Board currently has one full time position for secretarial assistance and has the part-time assistance of one of the secretaries of the Division of Drug Control.

(Editor's Note: Since this Report, Mr. Anthony Padussis has been appointed to the Board and Mr. Bernard Lachman has been elected President. Mr. I. Earl Kerpelman is now Honorary President.)

#### **EXAMINATION**

The Board conducted two examinations for registration of pharmacist during the fiscal year. They were held at the School of Pharmacy of the University of Maryland on October 12, 13 and 14, 1977 and June 28,29 and 30, 1978.

There were 49 applicants for the full Board in November. Thirty-five passed both the theoretical and practical portions of the examination and were subsequently registered. Thirteen failed the examination. One applicant did not appear for the examination. Having previously passed the theoretical portion of the examination, eleven candidates took the practical examination in October. All of these candidates passed and were subsequently registered. One applicant took only the theoretical portion of the examination, which he passed and will take the practical examination upon completion of practical experience required. One applicant took only the practical portion of the examination, as he did not have the required experience for reciprocity. This applicant passed the practical portion and was subsequently registered by reciprocity.

Data relative to the June, 1978 examination is not available at this time.

The Standard Examination of the National Assocition of Boards of Pharmacy was given, which consisted of the following subjects:

Chemistry Pharmacy Mathematics Pharmacology Practical Pharmacy The Jurisprudence examination which was compiled by a member of the Board was given as a part of the practical portion of the examination, as well as the compounding of three prescriptions per applicant.

The following table shows the number of pharmacists who were registered by examination during the past ten

years:

Year	Number of Pharmacists
1968-1969	60
1969-1970	93
1970-1971	112
1971-1972	133
1972-1973	96
1973-1974	111
1974-1975	113
1975-1976	109
1976-1977	166
1977-1978	150

As in the past many pharmacists applied for reciprocal registration in Maryland in order to accept position with their employers who are opening stores in Maryland. Those applicants who did not meet our requirements concerning practical experience prior to or after registration were advised that they must take our practical examination in order to verify their qualifications.

In all cases an applicant for reciprocal registration must appear for a personal interview. The entire Board must act on whether or not to grant registration to such applicants, who must sign an agreement to comply with Maryland's law pertaining to drugs and pharmacy.

The following table shows the number of pharmacists granted registration by reciprocity and the number who were certified to register by reciprocity in other states during the past ten years.

Fiscal Year	Reciprocity	Certification
1968-1969	84	27
1969-1970	75	40
1970-1971	92	26
1971-1972	67	35
1972-1973	94	57
1973-1974	88	63
1974-1975	76	45
1975-1976	89	44
1976-1977	78	68
1977-1978	91	77
Total	834	482

The table shows Maryland gained 352 pharmacists by reciprocity during the past ten years.

#### **MANUFACTURERS' PERMITS**

Permits to manufacture drugs, medicines, toilet articles, dentifrices or cosmetics during 1978 were issued to 29 firms.

#### DANGEROUS DRUG DISTRIBUTORS' PERMITS

The Board issued 83 permits to sell, distribute, give or in any way dispose of dangerous drugs during 1978.

#### PHARMACY PERMITS

Location	1975-1976	1977-1978
Records not available for 197	76-1977	
Counties:		
Allegany	24	23
Anne Arundel	58	61
Baltimore	157	159
Calvert	3	5
Caroline	3	3
Carroll	17	19
Cecil	7	8
Charles	7	7
Dorchester	6	9
Frederick	17	17
Garrett	5	5
Harford	26	26
Howard	17	18
Kent	4	4
Montgomery	103	103
Prince George's	106	112
Queen Anne's	4	4
St. Mary's	6	6
Somerset	5	- 5
Talbot	6	8
Washington	21	20
Wicomico	13	13
Worcester	11	_11_
County Totals	626	646
Baltimore City	191	185
State-wide Totals	817	831

The above figures include permits issued to hospitals in the counties as follows:

Allegany	2	Harford	2
Anne Arundel	3	Howard	2
Baltimore	9	Kent	1
Calvert	\$	Mongomery	5
Carroll	3	Pr. George's	5
Cecil	- 1	St. Mary's	1
Charles	1	Somerset	1
Dorchester ·	2	Talbot	1
Frederick	1	Wicomico	1
		Total	45

In Baltimore City, 19 hospitals received a permit to operate a pharmacy. Thus, a total of 64 hospitals have a licensed pharmacy. Five nursing homes, one State Penal Institution and the Dental School of the University of Maryland have received pharmacy permits. Also, the first nuclear of the University of Maryland was issued a pharmacy permit during the past year.

#### LEGISLATION

The following legislation which effects the profession of pharmacy either directly or indirectly was enacted by the 1978 Maryland General Assembly and signed into law by Acting Governor Blair Lee, III.

Senate Bill #1223 Expands definition of the Practice of Pharmacy.

House Bill #227 Disciplinary power of the Maryland Board of Pharmacy.

The following bills failed, but are of interest to the Board:

Senate Bill #841 Mandate lower generic cost.

Senate Bill #1160 To require all dispensers of medication to properly label and package them.

House Bill #1477 Allows one or more consumers to the Board.

House Bill #197 Allow the Board to set their own

fees.

House Bill #400 Mandatory Patient Profiles.

House Bill #1082 Reguire the Board to register graduates of foreign pharmacy

schools.

House Bill #1904 Continuing Education.
Senate Bill #1072 Continuinge Education.

#### **COOPERATIVE ACTIVITIES**

The Board maintained membership in the National Association of Boards of Pharmacy. The annual meeting of the Association was held in New Orleans, Louisiana on April 22-26, 1978. The Board was represented by Mr. Robert E. Snyder, Mr. Bernard Lachman, Ms. Estelle G. Cohen and Mr. Leonard J. DeMino.

The Board also maintained membership in the Conference of Boards and Colleges of Pharmacy of the National Association of Boards of Pharmacy, District Number Two, comprising of the states of New York, New Jersey, Pennsylvania, Delaware, Maryland, the District of Columbia, Virginia and West Virginia. The Board was represented by President Ralph E. Quarles, Mr. Robert E. Snyder, Mr. Leonard J. DeMino, Ms. Estelle G. Cohen and Mr. Paul Freiman.

The Board maintained cooperative activities with the State Department of Health and Mental Hygiene, the School of Pharmacy-University of Maryland, the Maryland Pharmaceutical Association, the Federal Drug Enforcement Administration, the Food and Drug Administration, City, County and State Police and all boards and pharmacy schools throughout the country.

#### **FINANCES**

All funds of the Board of Pharmacy are deposited to the credit of the Treasurer of the State of Maryland and disbursements covering the expenses of the Board are paid by voucher by the State Comptroller.

Respectfully submitted,

Vaul Freman

Paul Freiman, Secretary-Treasurer MARYLAND BOARD OF PHARMACY

### APhA Offers Three New Publications

Computers in pharmacy, animal health, and supportive personnel are the focus of three new books published by the American Pharmaceutical Association, the national professional society of pharmacists.

Computers for Pharmacy — A Guide to their Selection and Use in Community Practice is edited by Judith E. Lauer, a well-known lecturer on computer systems application from the University of Colorado. In simple straightforward language, this new APhA publication explains how computers work and the terminology, what functions computers can perform, and the general kinds of systems available. Computers for Pharmacy (72 pages, 22 x 28 cm, soft cover) is available for \$12, \$8 for APhA members.

Animal Health Products: Design and Evaluation is edited by Dr. Donald C. Monkhouse, Pfizer, and prepared by the APhA Academy of Pharmaceutical Sciences. This book compiles for the first time in booklength form the concepts and ideas related to the development of drug products for animals. In addition, it serves as a reference text for teaching and defining future research trends (152 pages, 15 x 23 cm, soft cover, \$14, \$9 for APhA members).

For pharmacists who think they need help in their practices, APhA has published two Supportive Personnel Training Manuals.

The Pharmacist's Manual takes the pharmacist through the processes of practice analysis to determine if and where supportive personnel are needed, the job description, recruitment, orientation, training, and supervision (38 pages, 22 x 28 cm, soft cover, \$10, \$7 for APhA members).

The Trainee's Manual is the workbook used by the trainee during the training process. It gives step-by-step instructions and includes written text material as well as tests and background information (55 pages, 22 x 23 cm, soft cover, \$10, \$7 APhA members).

The set of both manuals is available for \$17, \$12 for APhA members.

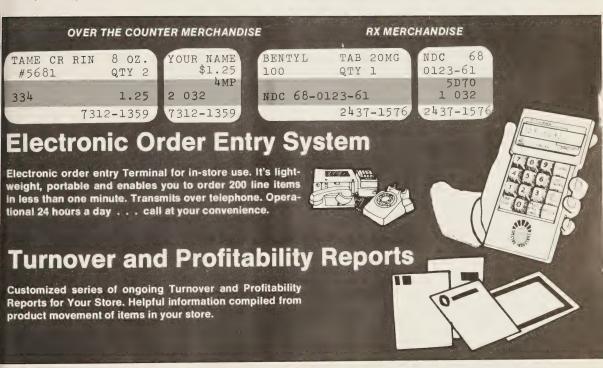
All of these new APhA publications can be ordered by sending check or money order to: APhA Order Desk, 2215 Constitution Ave., N. W., Washington, DC 20037. Orders totaling less than \$50 and all foreign orders must be prepaid. APhA members should include a mailing label from APhA Weekly or American Pharmacy to establish member identification.

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cephalosporin, or other allergies before treatment. If an allergic reaction occurs, discontinue the drug and treat with the usual agents (e.g., epinephrine or other pressor amines, antihistamines, or corticosteroids).

Precautions: Use with caution in individuals with histories of significant allergies and/or asthma. Do not rely on oral administration in patients with severe illness, nausea, vomiting, gastric dilatation, cardiospasm, or intestinal hypermotility. Occasional patients will not absorb therapeutic amounts given orally. In streptococcal infections, treat until the organism is eliminated (minimum of ten days). With prolonged use, nonsusceptible organisms, including fungi, may overgrow; treat superinfection appropriately.

Adverse Reactions: Hypersensitivity, including fatal anaphylaxis. Nausea, vomiting, epigastric distress, diarrhea, and black, hairy tongue. Skin eruptions, urticaria, reactions resembling serum sickness (including chills, edema, arthralgia, prostration), laryngeal edema, fever, and eosinophilia. Infrequent hemolytic anemia, leukopenia, thrombocytopenia, neuropathy, and nephropathy, usually with high doses of parenteral penicillin. [102176]

Additional information available to the profession on request.



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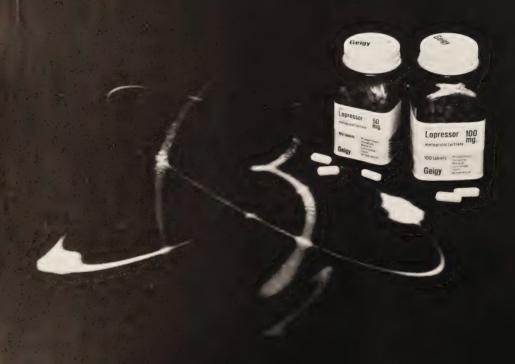
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Indications Lopressor, brand of metoprolol tartrate, is indicated in the management of hypertension. It may be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics.

Contraindications Lopressor, brand of metoprolol tartrate, is contraindicated in sinus bradycardia, heart block greater than first degree, cardiogenic shock, and overt cardiac failure (see Warnings).

Warnings Cardiac Failure: Sympathetic stimulation is a vital component supporting circulatory function in congestive heart failure, and beta blockade carries the potential hazard of further depressing myocardial contractifity and precipitating more severe failure. In hypertensive patients who have congestive heart failure controlled by digitalis and diuretics. Lopressor, brand of metoproloi tartrate, should be administered cautiously. Both digitalis and metoprolol slow AV conduction.

In Patients Without a History of Cardiac Failure continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, patients should be fully digitalized and/or be given a diuretic, and the response observed closely. If cardiac failure continues, despite adequate digitalization and diuretic, Lopressor, brand of metoprolol tartrate, therapy should be withdrawn.

Ischemic Heart Disease: Following abrupt cessation of therapy with certain beta-blocking agents, exacerbations of angina pectoris and, in some cases, myocardial infarction have been reported. Even in the absence of overt angina pectoris, when discontinuing therapy, Lopressor, brand of metoprolol tartrate, should not be withdrawn abruptly, and patients should be cautioned against interruption of therapy without the physician's advice.

Bronchospastic Diseases: PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL
NOT RECEIVE BETA BLOCKERS. Because of its
relative beta, selectivity, however, Lopressor, brand
of metoprolol tartrate, may be used with caution in
patients with bronchospastic disease who do not
respond to, or cannot tolerate, other antihypertensive treatment. Since beta, selectivity is not absolute, a beta,-stimulating agent should be administered concomitantly and the lowest possible dose
of metoprolol should be used. It may be prudent
initially to administer metoprolol in three doses
daily, instead of two, to avoid the higher plasma
levels associated with the longer dosing interval.
(See Dosage and Administration.)

Major Surgery: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Metoprolol, like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in restarting and maintaining the heart beat has also been reported with beta blockers.

Diabetes Mellitus: Beta-adrenergic blockade may mask symptoms of hypoglycemia (e.g., tachycardia) and may potentiate insulin-induced hypoglycemia. Lopressor, brand of metoprolol tartrate, should therefore be used with caution in diabetic patients, especially those with labile diabetes.

## The relatively selective beta blocker with b.i.d. dosage for hypertension

Thyrotoxicosis: Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyper-thyroidism. Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta blockade which might precipitate a thyroid storm.

Precautions Impaired Hepatic or Renal Function: The drug should be used with caution in patients with impaired hepatic or renal function.

Drug Interactions: Catecholamine-depleting drugs (e.g., reserpine) may have an additive effect when given with beta-blocking agents. Patients treated with Lopressor, brand of metoprolol tartrate, plus a catecholamine depletor should therefore be closely observed for evidence of hypotension and/or marked bradycardia which may produce vertigo, syncope, or postural hypotension.

Long-Term Animal Studies: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In a one-year study in dogs, there was no evidence of drug-induced toxicity at or below oral doses of 105 mg/kg per day. Two-year studies in rats at three oral dosage levels of up to 800 mg/kg per day did not indicate an increase in the development of spontaneously occurring benign or malignant neoplasms of any type. The only histologic changes which appeared to be drug-related were an increased incidence of generally mild focal accumulation of foamy macrophages in pulmonary alveoli and a slight increase in biliary hyperplasia. Neither finding represents symptoms of a known disease entity in man. In a 21-month study in mice at three oral dose levels of up to 750 mg/kg per day, benign lung tumors (small adenomas) occurred more frequently in female mice receiving the highest dose than in untreated control animals. There was no increase in malignant lung tumors or total (be-nign plus malignant) lung tumors. The overall incidence of tumors or malignant tumors was also unaffected by metoprolol administration.

Usage in Pregnancy: Reproduction studies in animals did not reveal any evidence of impaired fertility or of teratogenic potential. There was evidence in the rat of increased postimplantation loss and decreased neonatal survival (threshold between 50 and 500 mg/kg). Distribution studies in mice confirm exposure of the fetus when metoprolol is administered to the pregnant animal. There are no well-controlled studies in pregnant women. Lopressor, brand of metoprolol strartate, should be used in pregnant women only when clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Since most drugs are excreted in human milk, nursing should not be undertaken by mothers receiving metoprolol.

Usage in Children: Safety and effectiveness in children have not been established.

Adverse Reactions Most adverse effects have been mild and transient.

Central Nervous System: Tiredness and dizziness have occurred in about 10 of 100 patients. Depression was reported in about 5 of 100 patients. Headache, nightmares, and insomnia have also been reported but drug relationship is not clear.

Cardiovascular: Shortness of breath and bradycardia have occurred in approximately 3 of 100 patients. Cold extremities, Raynaud's disease, palpitations and congestive heart failure have been reported. See Contraindications, Warnings, and Precautions.

Respiratory: Wheezing (bronchospasm) has been reported in less than 1 of 100 patients. See Warnings.

Gastrointestinal: Diarrhea has occurred in about 5 of 100 patients. Nausea, gastric pain, constipation, flatulence, and heartburn have been reported in 1 of 100 or less than 1 of 100 or less than 1 of 100 or less than 1 or 100 o

Allergic: Pruritus has occurred in less than 1 of 100

**Miscellaneous:** Peyronie's disease has been reported in less than 1 of 100,000 patients.

The oculomucocutaneous syndrome associated with the beta blocker practolol has not been reported with Lopressor, brand of metoprolol tartate, during investigational use and foreign marketing experience.

Potential Adverse Effects: In addition, a variety of adverse effects not listed above have been reported with other beta-adrenergic blocking agents, and should be considered potential adverse effects of metoprolol.

Central Nervous System: Reversible mental depression progressing to catatonia; visual disturbances, hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Cardiovascular: Intensification of AV block (see Contraindications).

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Allergic: Erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory

Miscellaneous: Reversible alopecia.

Clinical Laboratory Test Findings: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

Dosage and Administration Dosage of Lopressor, brand of metoprolol tartrate, should be individualized The usual initial dose is 50 mg twice daily whether used alone or added to a diuretic. The dosage may be increased at weekly (or longer) intervals until optimum blood pressure reduction is achieved. In general, the maximum effect of any given dosage level will be apparent after one week of therapy. Usual maintenance dosage is approximately 100 mg twice a day, with a range of 100 to 450 mg per day. Dosages above 450 mg per day have not been studied. While twice-daily dosing is effective and can maintain a reduction in blood pres sure throughout the day, some patients, especially when lower dosages are used, will experience a modest rise in blood pressure toward the end of the 12-hour dosing interval. This can be evaluated by measuring blood pressure near the end of the dosing interval to determine whether satisfactory control is being maintained throughout the day. If control is not adequate, a larger dose, or three times daily therapy, may achieve better control. Beta, selectivity diminishes as dosage of Lopressor, brand of metoprolol tartrate, is increased.

This drug should be stored at controlled room temperature and protected from moisture.

How Supplied Tablets of 50 mg (capsule-shaped, scored, light red, film-coated) and 100 mg (capsule-shaped, scored, light blue, film-coated) are supplied in bottles of 100 and 1,000 and Unit Dose Packages of 100

Store at controlled room temperature and protect from moisture. 667290 (8/78) C78-38

Before prescribing or administering, please consult complete product information.

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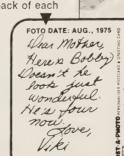
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## **Drug Abuse Directory**

Compiled by Ira Fedder

The situation will arise in all aspects of pharmacy practice when a patient will approach you with a question concerning social drug use or drug abuse. The pharmacist being an easily accessible practitioner should be able to answer these questions or provide the appropriate referral such that these questions can be answered. In an effort to provide continuing education to the practicing pharmacist and to disseminate information to the public. an abbreviated directory of drug abuse treatment facilities and agencies which provide services to drug abusers and their families is being published in this issue of the

Maryland Pharmacist.

The list of agencies offering services to drug abusers has been condensed from a publication entitled "A Directory of Drug Abuse Treatment Programs and Organizations Offering Services to Drug Abusers", June, 1977. The complete directory can be obtained from the Maryland Dept. of Health and Mental Hygiene, Drug Abuse Administration, Herbert O'Connor Bldg., 4th Floor, 201 West Preston Street, Baltimore, Maryland 21201. Telephone (301) 383-3312.

#### BEFORE USING THE DIRECTORY READ THESE INSTRUCTIONS:

- 1. Utilize all community resources. The directory is published only as a guide to obtaining assistance in dealing with drug abuse problems. The directory does not include all agencies, organizations and volunteer groups which may offer services to persons with drug abuse problems.
- 2. The directory was published in June, 1977. Therefore before referring a patient to any agency it is imperative that you verify the agency's phone number and address.
- 3. When calling a referral agency for assistance try to ask them specific questions. Many referral sources need to know what drugs are being used, the age of the patient and possibly the patient's address.
- 4. Remember information obtained from a patient is CONFIDENTIAL. Assure the patient of the confidentiality of the patientpharmacist relationship.
- 5. The Student Committee on Drug Abuse Education (SCODAE) at the University of Maryland School of Pharmacy offers a Drug Information Service. The Committee will respond to questions from health care professionals as well as the lay public. Persons with questions should call SCODAE. Telephone (301) 528-7513.
- 6. Questions concerning toxicology (overdoses and poisonings) should be referred to the Maryland Poison Information Center. Telephone (301) 528-7701 or outside the Baltimore metropolitan area (toll-free) 1-800-492-2414
- 7. Contact your nearest office of Alcoholics Anonymous. AA is an excellent resource for both the alcoholic and their family.

ALLEGANY COUNTY Allegany County Health Dept. c/o Addictions Program P.O. Box 690 Willowbrook Rd. Cumberland, Md. 21502	777-5635
Community Counseling Center Memorial Hospital Medical Bldg. 530 Memorial Ave. Cumberland, Md. 21502	777-1509
ANNE ARUNDEL COUNTY Anne Arundel County Health Dept.	224-7366
Open Door 62 Cathedral St. Annapolis, Md. 21401	224-1877
Open Door North 12-U Crain Highway, N.E. Glen Burnie, Md. 21061	760-6591
Annapolis Youth Service Bureau 92 W. Washington St. Annapolis, Md. 21401	224-7507
Glenarden Youth Services and Referra 8427 Hamlin St. Glenarden, Md. 20801 772-0120	772-0194
BALTIMORE CITY Contact-Baltimore, Inc. (hotline, 24 hrs. a day)	332-1114
Hand in Darkness Hotline, Inc. 4708 Harford Rd. P.O. Box 3635 Baltimore, Md. 21214	254-4720 (office) 254-6040 (hotline)
Provident Community Mental Health Control 1900 Eutaw St.	(
Baltimore, Md. 21217 The North Baltimore Center, Inc.	523-5226
100 East 23rd St. Baltimore, Md. 21218	366-4360

Walter Carter Center 630 W. Fayette St. 528-2267 (hot Baltimore, Md. 21201	line 24 hrs/day) 528-2206
Cherry Hill Mental Health Center 2490 Giles Rd. Baltimore, Md. 21225	528-2286
Carruthers Mental Health Center 112 East West St. Baltimore, Md. 21200	383-2900
Morley Street Mental Health Center 251 South Morley St. Baltimore, Md. 21229	528-2144
Neighborhood Adolescent and Young Add	ult Program
1515 Bruce St. Baltimore, Md. 21217	523-3000
Sinai Hospital Dept. of Psychiatry Belvedere and Greenspring Ave. Baltimore, Md. 21205	67-7800 x. 8841
BALTIMORE COUNTY Brotherhood of Man, Inc. 517 Virginia Ave. Towson, Md. 21204	823-4357
Epoch House 22 Bloomsbury Rd. Catonsville, Md. 21228	747-0243
Epoch House East 307 Eastern Ave. Essex, Md. 21221	574-2500
Eastern Community Mental Health Center	374-2500
9100 Franklin Square Dr. Baltimore, Md. 21237	687-6500
9100 Franklin Square Dr.	687-6500 788-5483

People for Community Action Youth Services Bureau 1707 Taylor Ave. Baltimore, Md. 21234 665-3330

CAROLINE COUNTY

Caroline County Health Dept. 411 Franklin St

479-0556 Denton, Md. 21629

CARROLL COUNTY

Carroll County Youth Services Bureau, Inc. Suite #10 Carroll Plaza Shopping Center Westminster, Md. 21157

848-2500

CECIL COUNTY Cecil County Health Dept.

Drug Dependency Clinic Courthouse Elkton, Md. 21921

398-5106

662-8911

838-2520

CHARLES COUNTY

Tri County Youth Services Bureau P.O. Box 101 274-3105 884-4141 Hughesville, Md. 20637 257-3027

The Bumpy Oak Center Box 2287 — Y Route 2 La Plata, Maryland 20646

DORCHESTER COUNTY

Upper Shore Counseling, Evaluation and Referral Service Talbot County Health Dept. P.O. Box 480

South Hanson St. Easton, Md. 21601

822-6650

FREDERICK COUNTY Frederick County Drug and Alcohol Walk-In Center

101 South Market St. 662-8921

Frederick, Md. 21701

Project 103 Frederick County Drug Information

and Counseling Service 2-B Catoctin Ave.

Frederick, Md. 21701

GARRETT COUNTY Youth Counseling Services Garrett County Health Dept.

228 E. Alder St. Oakland, Md. 21550 334-8111

HARFORD COUNTY

Harford County Drug Abuse Program Harford County Health Dept.

125 N. Main St.

P.O. Box 191 Bel Air, Md. 21014

Harford County Drug Abuse Program Perceptions Counseling Center

101 Wilson St. Havre de Grace, Md. 21078.

939-5454

HOWARD COUNTY Grassroots

5829 Banneker Rd. 730-3090 (Clients) Columbia, Md. 21044 Hotline 24 hrs/day

Drugs and Alcohol Abuse Center Howard County Health Dept.

8293 Main St

Ellicott City, Md. 21043 465-5000 ext. 378

KENT COUNTY Help Line

Public K. House

301 High St. 778-2616

Chestertown, Md. 21620 778-4357 (Hotline)

Kent County Health Dept. P.O. Box 359

Chestertown, Md. 21620 778-1350

MONTGOMERY COUNTY Drug Action Coalition

50 Monroe St. Rockville, Md. 20850 340-0400 (Hotline)

c/o Mental Health Association of Montgomery County

10920 Connecticut Ave. Kensington, Md. 20795

949-6603 (Hotline 24 hrs/day)

Montgomery General Hospital Community Mental Health Center

18101 Prince Phillip Dr

Olney, Md. 20832 774-7800 ext 206 Youth and Family Counseling Program

Passage Crisis Center 8500 Colesville Rd. 587-4565 Silver Spring, Md. 20910 589-8608 (Hotline 24 hrs/day)

PRINCE GEORGE'S COUNTY

Box 535

Bowie, Md. 20715 262-AIDE (Hotline)

Prince George's County Hotline and Hidden Entrance 6100 Rhode Island Ave.

Riverdale, Md. 20840 864-7271 (Hotline 24 hrs/day)

New Carrollton Counseling Center

7900 Riverdale Rd.
White Trailer — Woolco Parking Lot

577-0334 New Carrollton, Md. 20904 459-7979

Palmer Park Counseling Center

7711 Barlow Rd. Palmer Park, Md. 20785 772-5414

Prince George's General Hospital

Chemical Dependency Treatment Unit, H-300 Dent of Psychiatry

Cheverly, Md. 20785

341-3300 ext. 2485

Surrattsville Community Counseling Center 6302 Aaron Lane

Surrattsville, Md. 20735

868-5600 Temple Hills Counseling Center

4911 St. Barnabas Rd.

894-5169 Temple Hills, Md. 20031

QUEEN ANNE'S COUNTY

Upper Shore Counseling, Evaluation and Referral Service Talbot County Health Dept.

P.O. Box 480 South Hanson St

Easton, Md. 21601 822-6650

ST. MARY'S COUNTY

Walden Counseling Center Southern Maryland Drug Abuse Program

Box 224

California, Md. 20619

St. Mary's County Mental Health Programs County Health Dept.

6 Lincoln Dr.

Lexington Park, Md. 20653 863-7092

SOMERSET COUNTY Somerset/Wicomico/Worcester Drug Education,

Counseling, Treatment and

Rehabilitation Program Wicomico County Health Dept.

300 West Carroll St. Salisbury, Md. 21801 742-9318 ext. 20

TALBOT COUNTY

Upper Shore Counseling, Evaluation and Referral Service

Talbot County Health Dept. P.O. Box 480

South Hanson St. Easton, Md. 21601

822-6650

WASHINGTON COUNTY

Center for Drug Abuse Assistance

1309 Pennsylvania Ave. Hagerstown, Md. 21740 791-2600 (HELP-LINE)

791-3240

Oak Hill House 653 Oak Hill Ave.

Hagerstown, Md. 21740

797-4569

WICOMICO COUNTY

Somerset/Wicomico/Worchester Drug Education, Counseling, Treatment and

Rehabilitation Program Wicomico County Health Dept.

300 West Carroll St.

Salisbury, Md. 21801 742-9318 ext. 20

WORCESTER COUNTY

Alcohol and Drug Clinic Greater Ocean City Health Service Corporation

P.O. Box 470

Berlin, Md. 21811

Youth Health Center (Open May 30 to Labor Day) Caroline St. and the Boardwalk

289-4044 Ocean City, Md.

Somerset/Wicomico/Worcester Drug Education,

Counseling, Treatment and Rehabilitation Program

Wicomico County Health Dept. 300 West Carroll St.

Salisbury, Md. 21801 742-9318 ext. 20

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## INTPARTANSION AND THE SECRETS OF ACTIVE

Why does hypertension affect such large numbers of the elderly

population?

Clinicians have argued that hypertension "...is as much a part of the aging process as the changes that occur in hair, teeth, eyes and

skin." Or is it?

Certainly organic and functional vascular changes occur with age which may stimulate the development of hypertension. Lipid accumulations occur in arteries, and vessels lose elasticity. As a result of this, the arterial pressure rises, accelerating the atherosclerotic process. This, in turn, aggravates hypertension. The older an individual becomes, the more likely these events will occur and the more likely an individual will have hypertension.

Laragh<sup>2</sup> and others<sup>3</sup> have proposed that essential hypertension is really more than one disease – and that the key to deciphering those different diseases lies in deciphering the renin concentration code. Now, a new use for renin activity measurement has surfaced: observation of these particularly sensitive hormonal mechanisms can illuminate the aging

process.

A study by Crane and Harris<sup>4</sup> measured PRA (plasma renin activity) in groups of adults in each decade of life from 20-79. They found that PRA declined with increasing age and that the values of those over 70 were only 60% of that of the younger age group.

In an earlier study by Crane and Harris, where renin activity response to sodium restriction was measured, many of the elderly (53%) had an abnormal response. The entire regulating mechanism, they infer, is less finely tuned with advancing age.

Another discussion of the relationship between hypertension and aging appeared in 1976 in *Geriatrics*. 5 As a result of the observed regulation of blood pressure by monaminergic nerves and the reduction of blood pressure by blocking agents which alter peripheral resistance, Saul Kent speculated that hypertension is a consequence of a generalized neuroendocrine malfunction of aging. Kent also stated that since blood volume, blood viscosity, cardiac output,



elasticity of arterial walls, and peripheral resistance all contribute to the regulation of blood pressure, a change in any one of these components may increase pressure. Such a change may occur through the documented<sup>6</sup> gradual loss of functioning cells from organs and tissue that occurs with aging.

In summary, it appears serum value reductions of renin and aldosterone, generalized neuroendocrine malfunction, increased atherosclerosis, and the concurrent incidence of hypertension itself in the elderly are outgrowths of the natural aging process. Exactly what that process is, whether it can be slowed or even reversed, and what secrets it can reveal, however, remain to be seen.

#### References

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# ASPIRIN Its Multiplicity of Side Effects

by
John C. Krantz, Jr., Ph.D.
Professor Emeritus
Department of Pharmacology
University of Maryland
School of Medicine

There is no drug available that cannot be improved upon. The action of most drugs is accompanied by side effects. These may be intolerable and render the therapy unbearable or may be of such minor character that the patient is unaware of their occurrence. Indeed, certain drugs elicit side effects that can be useful in therapy as their principal action. A classical example is that of the anithistamines that have been found useful in the treatment of insomnia. The principal use of aspirin depends upon its value as an analgesic and anti-inflammatory agent. In this use minor gastric intolerance is sometimes encountered that is obviated by well-buffering the drug and the ingestion of much water with the tablet.

When the dosage of aspirin is increased other interesting side effects appear such as the reduction of blood-chloesterol levels<sup>1</sup> and the lowering of blood-sugar levels.<sup>2</sup> Each of these side effects may be beneficial to selective groups of patients.

Another side effect of aspirin is production of microbleeding of the gastric mucosa. The patient is unaware of this effect and it can be avoided by well-buffering the aspirin and taking the dose with much water.

Another most striking side effect of aspirin is upon blood platelets. The drug diminishes the aggregation of platelets which is a step in the initiation of the clotting process. Weiss<sup>3</sup> in 1967 observed that the ingestion of small doses of aspirin caused a minor increase in the bleeding time of normal subjects. This was due to the effect of aspirin upon the aggregation of platelets. This observation suggested the possibility of the use of this side effect of aspirin in the prevention of diseases owing to the clotting of the blood in the brain, heart or other organs. Other drugs, such as phenylbutazone and indomethacin, also evoke the inhibiting action on platelet aggregation, but aspirin offers the optimal use for mass medication, presenting the greatest ratio of benefit/risk.

It is of interest that this is not the action of salicylic acid as sodium salicylate does not produce the effect. It appears that the acetyl group in aspirin is the functioning factor. It acetylates the platelet and prevents the aggregation process. Indeed, the acetylation endures throughout the life of the platelet, 4-7 days.

Our knowledge of the mechanism of the action of aspirin in the prevention of platelet aggregation is in a state of flux. It is generally agreed that it is concerned with its effect upon the prostaglandins which enjoy a multiplicity of roles in many tissue functions. PGX, one of the most recently isolated prostaglandins, plays a key role in the prevention of platelet aggregation. It is postulated that platelets impinging upon the inner lining of blood vessels release prostaglandin endoperoxide PGE<sub>2</sub>. This causes platelet aggregation. Simultaneously the cell wall releases an enzyme which converts the endoperoxide to PGX, thus preventing platelet clumping

Aspirin, indomethacin and other anti-inflammatory drugs appear to block the conversion of arachidonic acid to PGE<sub>2</sub>, that causes platelet aggregation. This allows PGX to function uninhibited in its capacity to prevent platelet aggregation. It is clear that our understanding of this intricate mechanism is still in its incipiency and much work will be required before our knowledge of it is complete.

Of special interest is the ability of the aggregation to be initiated by alternative pathways so that hemostasis is not impaired in the normal person.

Reports are available from many clinical centers indicating the value of aspirin in the prevention of vascular accidents. For example, in 1974, British investigators<sup>5</sup> reported that 600 heart attack patients who had taken one aspirin daily had 25 percent fewer heart attacks than those who had taken a placebo. The evidence at hand bespeaks the benefit/risk ratio for mass medication is high. It would appear that individuals who have suffered a heart attack or "little stroke" might reduce their chance of a second ipisode by the ingestion of aspirin daily.

Whether or not it would be prudent for all persons in middle-life and after to daily ingest aspirin to guard against a vascular accident is problematic at present. One must wait until many more results are available from the present ongoing studies.

If Felix Hoffman, who introduced aspirin into medicine at the turn of the century, were alive and viewed the expanding spectrum of the action of the drug he would be greatly gratified.

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- 2. Reid, J. and J.D. Lightbody; Brit. Med. J., 4:897, 1959
- 3. Weiss, H.J. and L.M. Aledort; Lancet, 2:495, 1967
- 4. Vane, J.J.; C & E, 54 (50):17, 1976
- 5. Elwood, P.C., A.L. Cochrane et al.; Brit. Med. J., 1:436, 1974



### Federal Debt Collection Law Make Expensive Demands

The most important challenge facing the collection industry in 1978 is adaptation to the new FAIR DEBT COLLECTION PRACTICES ACT which takes effect on March 20, 1978. Although its primary stated purpose is to curb harassment and abuse of the consumer, this is not its most significant aspect. Legitimate collection people don't rely on unethical tactics anyway. More important to the industry are the expensive and detailed systems and procedures a collection agency must employ in order to comply.

Perhaps the most significant new procedural requirements provide for enforced two-way communications between debtor and collection agency. Collection agencies must now stop collection activity upon written demand and respond to specified debtor questions and complaints. It is no longer permitted to ignore communications from the debtor and simply hammer away at demanding payment.

Fortunately these requirements pose no new problems for the association approved collection service provided by I.C. System. Their highly sophisticated computer system enables them to come into full compliance by making minor adjustments rather than sweeping changes. As a result, their complete service remains available to members, and — at no increase in cost. For example, members can benefit from I.C. System's free pre-collection system just as they have in the past, with no changes required. Similarly, members can continue sending in accounts of any age or size. No account is too small or too old to handle under the new laws. Finally, there is no need to fear legal repercussions.

The new federal law applies only to collection agencies and to creditors who send out forms or correspondence or otherwise lead debtors to believe that a third party is involved in the collection process when, in fact, the creditor is doing the job himself. I.C. System provides no materials that would bring a client under the law and their hold harmless indemnity agreement protects both the association and its members from liability for any acts committed by the company in its collection activity.

The company, now in its 40th year in the collection business, is living proof that collection work can be carried on effectively, both by telephone and through the mail, within Federal Trade Commission guidelines and the laws of the various states. During 1977 I.C. System collected a record \$22.6 million for members of nearly 1,000 business and professional associations. Working within the new law should pose few difficulties.

There are some aspects of the new law which may open the door to abuse by the debtor who learns to "use the law" for his own purposes. By and large, however, I.C. System applauds this legislation as a step in the direction of upgrading the collection industry as a whole. It calls a halt to the kinds of practices that are neither necessary for effective debt collection, nor desirable as elements woven into the fabric of American business.

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Sept. 10 — Upper Bay Pharmaceutical Assn. Crab

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Sept. 17-21 — NARD Convention, New Orleans

Sept. 17 — MPhA Benefit Dinner Theatre, Colony 7

Oct. 5 — Balassone Memorial Lecture

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Jan. 13, 1979 — Winter Trip to St. Martin

Feb. 11, 1979 — BMPA Installation Banquet

# University of Maryland School of Pharmacy

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### ASCO, Inc. Enters Home Health Care Field

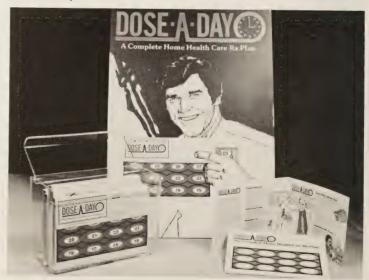
Recognizing that patient compliance with prescribed drug regimens is one of the most challenging problems for today's pharmacist, ASCO, Inc. has introduced an innovative new home health care plan called DOSE-A-DAY.

According to Erwin Brown, President of the Silver Spring, Maryland firm, the DOSE-A-DAY Home Health Care Plan incorporates five basic steps for improved patient compliance:

- 1. Initial interview with patient.
- 2. Comprehensive patient medication profile.
- 3. Pharmacists' reminder file for refill dates and new prescriptions.
- 4. The DOSE-A-DAY Calendar Pack for medication.
- 5. Periodic consultation with the patient.

The heart of this health care plan is the DOSE-A-DAY Calendar Pack. Each pack is filled and sealed in the pharmacy and contains 31 doses of medication, numbered to correspond with the day of the month. This unique packaging offers an automatic reminder system to the patient and a quick, easy method for the pharmacist, patient's nurse or relatives to monitor compliance.

Mr. Brown also indicates that the DOSE-A-DAY Plan is ideally suited for use in the home health care business. "This plan is an excellent way for the pharmacist to establish himself as an integral part of the home health care team."



### A Look Backward at MPhA Conventions

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SEPTEMBER, 1978



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### THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association

OCTOBER, 1978 VOL. 54 NO. 10



Skin Disease and its Treatment

Joint Membership Requirements Suspended for MPhA/APhA

Operating the Prescription

Department at a Profit

- Bruce R. Siecker, Ph.D., R.Ph.

### THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET **BALTIMORE MARYLAND 21201** TELEPHONE 301/727-0746



OCTOBER 1978

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NO. 10

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### Let The Third Parties Know How You Feel

The Association often hears complaints about the treatment Pharmacists receive at the hands of the third parties, *but is anyone telling them?* If you have a complaint, let them know. Be sure to send the Association a copy of your letter. It is only through this kind of cooperation and communication that we can get our message across. Take the time to do it now.

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### Skin Disease and Its Treatment

A Background Paper from Upjohn

#### I. INTRODUCTION

More than 25 million Americans suffer from one or more skin diseases, according to a report from the U.S. Department of Health, Education and Welfare. The number remains relatively constant from year to year.

The plethora of magazine and television advertisements for ointments and shampoos for skin diseases testifies both to their prevalence and to the lack of satisfactory treatment for most.

For many skin diseases, the cause is unknown. Others are associated more or less reliably with heredity, allergy, metabolism, underlying disease or chronic injury. Some, like psoriasis and eczema, are noninfectious; others are caused by bacteria or fungi and can spread from one part of the body to another or from person to person.

Many skin diseases are chronic and incurable. They can flare up and spread to new areas of the body or they can enter periods of inactivity, both without apparent cause. Some disappear completely after many years with no explanation.

Physicians can treat flare-ups and prescribe therapy to make patients comfortable, minimize symptoms and control the dermatoses.

A large percentage of skin disease sufferers, however, must adjust to a lifetime of bouts with intense itching, burning and pain from their disease. They must also live with the fact that because of the appearance of their faces, limbs and bodies, they may be the objects of the curiosity or aversion of others.

A multitude of terms such as eczema and dermatitis are used to describe the more common noninfectious inflammatory skin disorders. However, these disorders are generally called the eczematous dermatoses; among the conditions falling into this category are seborrhea, atopic dermatitis, neurodermatitis, contact dermatitis, allergic dermatitis and nummular dermatitis.

#### II. TREATMENT

Over the years, dermatologists and other physicians have developed regimens of baths, compresses, radiation treatments, medicines and modes of living to alleviate the suffering of patients with skin diseases. Pharmaceutical firms have responded to the needs of these persons by developing drugs of increasing efficacy and convenience in use.

For persons with skin diseases, baths often involve lukewarm water only, with a minimal exposure to soap or hot water. Over-the-counter or home remedies play little part in therapy.

Compresses of clean cotton cloths soaked in five percent aluminum acetate (Burow's solution) are remarkably helpful to alleviate itching and inflammation and to prevent bacterial or fungal infection.

Grenz radiation treatments often are beneficial. Grenz radiation is a form of energy that is more powerful than ultraviolet and is classed as mild x-ray. Treatments are usually given for 15 minutes a week for three to five weeks and repeated, if needed, after six months.

Steroid ointments, creams, lotions and gels are frequently employed medicines for the noninfectious dermatoses. Steroids such as hydrocortisone are the body's natural messenger substances for regulating metabolism. Pharmaceutical firms also have developed synthetic steroids that are more effective than the natural substances.

Topical steroids range from low to high potency and act by reducing inflammation of skin lesions, minimizing itching and constricting blood vessels. Often, they are used to break the itch-scratch cycle.

Because the majority of the noninfectious skin diseases like contact or allergic dermatoses are usually short-lived, topical therapy is often short-term. Some conditions, however, can rebound with acute flares or chronic patterns.

Among the side effects physicians watch for with patients on topical steroid therapy are striae (streaks) skin atrophy or possible systemic effects. Therapy is often tailored to the individual patient's needs, using the smallest amount possible.

Symptoms of skin disease often rebound with increased intensity after abrupt cessation of steroid therapy. Physicians, therfore, taper off doses of steroid by prescribing increasingly smaller amounts of progressively weaker strength preparations after acute phases of the disease are controlled.

Oral or injectable steroid drugs may be prescribed for certain types of severe cases, but physicians must be on guard against side effects and the possibility of rebound of severe symptoms if oral steroids must be abruptly discontinued. Topical steroid medications can be designed to require only once daily application for many diseases. Such formulations enable many patients to apply them only at bedtime, relieving them of the worry of soiling clothing or having to carry the medication with them and find time to apply it in private during a busy workday.

A complete description of treatment for all skin diseases is beyond the scope of this paper. What follows is an account of the symptoms, proposed causes, natural courses and treatments of certain such diseases of most interest today.

### III. INTENSE ITCHING (PRURITUS)

Though pruritus (intense itching) is the name of a symptom, diseases such as lichen (LIE-ken) simplex chronicus, pruritus ani and otitis externa are classed as pruritus. It is thought that skin diseases or infections may release protein-dissolving enzymes that irritate nerve endings that normally sense heat, cold and pain. These nerve endings, deranged by some mechanism, then produce itching from irregularity of signals sent to the brain.

### A. Lichen simplex chronicus

Lichen simplex chronicus, sometimes also called localized neurodermatitis, is caused by an insect bite, a rubbing collar, a habit of scratching some spot, stress, anxiety or underlying disease. The most common location is the back of the neck or the limbs, but it can occur anywhere. The susceptible person rubs or scratches the area constantly. This produces lichenification. Lichenification is a thickening of the skin with accentuation of surface lines and appearance of discolored, dry, closely-set bumps. Lichenified skin is supersensitive to further itching, setting up a vicious circle.

For unknown reasons, the disease is three times more common in women than in men and seven times as common in Orientals as in Occidentals. It is rare in children.

Treatment aims principally at relieving the vicious itch-scratch cycle. Steroid creams, ointments or gels are used at the beginning. The best technique is to use these under plastic film dressings changed daily. Weekly injections of steroids into the lichenified spot for three weeks is used for stubborn cases. Grenz radiation treatments are helpful. A heavy bandage impregnated with gelatin and zinc oxide is also effective to reduce itching and prevent the patient from scratching and rubbing the spot.

### B. Anal itching (pruritis ani)

Anal itching (pruritis ani) can be a specific manifestation of seborrheic, atopic or contact dermatitis; lichen simplex chronicus; fungal, pinworm or gonorrheal infection; psoriasis; warts; hemorrhoids; abscesses; rectal cancer; diabetes; kidney disease; or stress or anxiety.

In addition to treatment of the specific cause, general measures for managing pruritus ani involve a strict regimen to avoid irritation, plus weight loss if necessary. The patient must clean away fecal mate-

rial regularly with minimal amounts of unmedicated soap and take a 10- to 15-minute sitz bath daily in lukewarm water with no soap or rubbing. He or she must avoid patent remedies, spicy foods, tight clothes and long periods of sitting. Applications of compresses of Burow's solution four times daily are followed with a steroid cream applied sparingly with no rubbing. Grenz radiation is helpful. A tranquilizer and the anti-itching drug trimeprazine may be prescribed to facilitate adequate rest.

### C. Ear inflammation (otitis externa)

Inflammation of the outer ear may result from contact exposure to humid, moist environments (as in swimming); seborrheic, atopic or contact dermatitis; lichen simplex chronicus; psoriasis; or bacterial infection.

It affects the outer one-third of the auditory canal and ear opening, but may spread to the projecting part of the ear, face and neck. Otitis externa begins with scaling redness, progresses to moist, oozing itching and finally ends in pain, tenderness and collection of fluid in the skin tissue.

Treatment revolves around relieving the itching, cautioning the patient not to insert cotton-tipped swabs or other objects into the ear and avoiding dressings or measures that would plug the congested ear opening.

Otitis externa with crusting and oozing caused by seborrheic dermatitis can be teated with compresses of Burow's solution, followed by sparing application of steroid cream. Steroid ear drops are also helpful.

### IV. CONTACT DERMATITIS

Allergic eczematic contact dermatitis is caused by toughing plants or substances to which individuals are sensitive. Poison ivy and poison sumac are irritating to almost everyone, but 25 to 60 percent of Americans are also allergic to these plants. Other plants that cause this allergic reaction are chrysanthemums, primulas, tulip and daffodil bulbs, hops, tobacco and ragweed pollen. It can also be caused by sensitivity to particular substances in metal, leather, cosmetics, patent medicines, clothes, soaps, dyes and rubber.

After exposure to the allergen, redness develops, followed by inflammation, moistness, collection of fluid in skin tissue, itchy bumps and rupturing blisters. Certain home remedies, friction, pressure and continued exposure to the allergen exacerbate the condition. Excessive rubbing, scratching or exposure of one spot to the allergen eventually can produce a thickened, dull, red, scaling area that is susceptible to any irritation and which can be a serious handicap.

This dermatitis is treated by washing the affected area with soapy water if this can be done very soon after exposure. A drying, alcoholic lotion is applied. For severe cases, steroid creams or ointments or oral steroids may be prescribed, tapering off the dose when the condition is controlled.

Contact dermatoses may be analyzed by taking a careful history, making deductions from the location of the area and taping minute patches of cotton cloth impregnated with suspect substances over an uninvolved area (patch tests). Based on identification of suspect allergens, care is taken to isolate the patient from further exposure.

Compresses of Burow's solution four times daily for 15 minutes are helpful for oozing, crusted lesions and may be followed by a steroid ointment. Oral steroids are used for severe cases, and the dose is gradually tapered off. The area must be protected from heat, soap and rubbing.

During recovery, skin pores are very susceptible to clogging. This produces sweat retention which, in turn, causes inflammation and itching. It is often mistaken for a recurrence of the dermatitis. Sweat retention is treated by loose, well-ventilated clothes, cool baths and overthe-counter lotions.

Allergic contact dermatitis is caused by development of cells in the bloodstream that recognize allergens as "foreign" and migrate to the exposed skin area to produce the reaction. It is thus distinguished from atopic dermatitis (see below), which involves development of antibodies to certain substances and is associated with hay fever and asthma.

### V. SEBORRHEIC DERMATITIS

Seborrheic dermatitis (skin inflammation associated with excess secretion of the natural skin lubricant, sebum) is a common, incurable ill-defined disorder of unknown cause. It occurs in infancy as cradle cap, and is the most common cause of dandruff in adults. Few Americans thus escape it.

This condition occurs in infants as intense itching, skin redness and yellowish, greasy scaling, especially in scalp and diaper areas. The areas most often affected in adults are the scalp, face, ear, skin behind the ear, middle chest, upper middle back, naval and genitals. It occurs sometimes in the eyelids, crotch or around the anus.

Seborrheic dermatitis is often associated with psoriasis (see below). Some cases so closely resemble both conditions that they are diagnosed as sebopsoriasis or psoriatic seborrheic dermatitis. They prove hardest to treat. True seborrheic dermatitis differs from psoriasis in that affected areas are less well defined, are inflamed and have less scaling.

Scalp conditions are treated with frequent shampooing followed by selenium sulfide lotion treatments. Over-the-counter lotions and shampoos containing zinc pyrithione often are effective. Steroid lotions and creams also help.

Outside and just inside the ear, steroid creams may alleviate symptoms. Steroid doses should be tapered off after the condition is controlled. They should never be applied with cotton-tipped swabs.

For acute conditions, compresses of Burow's solution are applied three times daily. Infections are controlled with a four- to five-day course of oral antibiotics or local application of an antibiotic preparation. Sedatives

or tranquilizers may be needed to help patients get restful sleep.

Ultraviolet radiation treatments are sometimes effective, but often not. Grenz ray treatments are usually helpful.

#### VI. PSORIASIS

Psoriasis is a difficult-to-control hereditary disorder involving over-production of skin tissue. It is named from Greek *psora*, meaning itch. It afflicts one person in every 100. Psoriasis usually begins in young adults and is rare in infants and the elderly. Pregnancy often produces remissions. Anxiety and stress often increase itching discomfort.

Psoriasis occurs as very red, well-defined, thickly scaled regions over prominent bones (elbow, knee, small of the back and in scalp, ear, genital and hand areas. When nails are affected, they are thickened, discolored, crumbling and sometimes partly lifted from the nail bed.

Psoriasis occurs in as many as 80 percent and as few as 17 percent of the members of affected families. Psoriasis is rare in American Indians, Eskimos and Japanese.

It can progress rapidly with great scaling activity and spread or enter unexplained periods of inactivity. It seems to improve in the summer and deteriorate in the winter.

Normal skin renews itself totally every 26 to 28 days by cell division in the lowest levels of the epidermis and migration of cells through skin layers to the surface. In active psoriasis, this renewal period is shortened to about four days. Interior cells normally divide once in 163 hours. This increases to once in 37.5 hours in psoriasis.

Psoriasis also may occur as drop-shaped lesions one to three weeks after a strep throat. Another form is noninfected pus-filled pimples. This form can produce symptoms of general illness if widespread and draining extensively. Psoriasis over finger and toe joints can produce a type of arthritis.

Skin injury or over-zealous treatment can provoke a serious complication called erythroderma. Erythroderma involves intense reddening and sloughing of outer skin from almost the entire body. Affected patients must be hospitalized to treat difficulties in temperature regulation and fluid balance. Death can occur from heart failure.

Psoriasis patients must avoid burns from sun or heat and irritation that may provoke new lesions. Physicians can treat thick, inactive lesions aggressively but must be cautious with acute, recent, spreading ones to avoid precipitation of erythroderma.

Treatment includes 15-minute daily baths with added coal tar solution followed by application of an ointment based on coal tar. Carbolic acid salt and coal tar shampoos are available for scalp conditions. Steroid ointments alleviate acute conditions, and beneficial effects can then be maintained by tapering off doses of steroids and substituting coal tar- or mercury-containing medicines. Steroid ointments are used sparingly in genital, anal and eyelid regions.

Oral steroids are effective against psoriatic arthritis and erythroderma, but are usually not used otherwise, because psoriasis symptoms may rebound suddenly if these drugs must be withdrawn.

For acute conditions, steroid creams can be used under plastic film dressings and be held in place by clothes, gloves or a shower cap. Steroids also can ve injected directly under psoriatic lesions.

Ultraviolet and grenz ray treatments are often helpful.

#### VII. ATOPIC DERMATITIS

Atopic dermatitis, also called generalized neurodermatitis, is a hereditary disease that occurs in infantile and adult forms, but usually disappears by age 30 for unknown reasons. Twenty percent of Americans have a family history of the disease. Of those afflicted, 70 percent have family histories of it. Hay fever afflicts 30 percent of those with atopic dermatitis. Twelve percent develop rapidly advancing cataracts at an early age. Many are sensitive to penicillin.

The infantile form occurs at birth or, in most cases, at four months. It causes a very itchy, dry, scaly, cracked, abraded skin inflammation in the face, scalp, neck and diaper areas. In half of the children affected, the disease disappears between two and four years, but may recur in the adult form. In the other half, the infantile progresses directly into the adult form.

In the adult form, red abraded areas with accentuation of skin markings occur on the inner surface of the elbow or rear of the knee joints and may also involve hands, feet and face. Localized forms can appear on the wrists, ankles, feet, crotch, anus or genitals. It worsens in winter and in excessively hot or cold climates and improves in summer. A move to a warm, dry, even climate is recommended for some patients.

The principal aim of treatment is to relieve intense itching, both to increase the patient's comfort and to prevent exacerbation caused by rubbing and scratching.

Patients should wear soft, light, cotton clothes, and play, work and sleep areas should be cool and wellventilated. They should take sponge baths daily and avoid hot, soapy showers. Irritating paints, solvents, cleaning products, dusts and aerosols should also be avoided. Compresses of Burow's solution for 10 minutes three times daily ease wet, crusted, localized lesions. Steroid creams can be applied three times daily. These may be applied under plastic film dressings over hands, joints and other local areas and changed once daily or once every three to four hours. Minimal doses of oral steroids may control difficult cases. Grenz radiation is

Oral trimeprazine or cyproheptadine are two drugs that relieve itching. Tranquilizers and antihistamines also are often used to help patients get adequate rest.

Two dire complications of atopic dermatitis are exfoliative dermatitis and varicelliform eruption. Like erythroderma, exfoliative dermatitis is an intense skin

reddening, coupled with scaling or sheeting off of almost the entire outer skin. It is caused by neglect or overzealous treatment of atopic dermatitis. The warm, moist, exposed skin is subject to infection with Staphylococcus aureus ("staph").

The patient suffers lack of energy, shaking chills and anxiety. Death may result from pneumonia, heart or liver failure or heart tissue or blood infection. It is treated by hospitalization, constant nursing, oily lotions and baths, antibiotics for susceptible organisms, maintenance of fluid balance and intravenous steroids.

Varicelliform eruption is caused by vaccination or herpes virus infection spreading from the bloodstream to the skin. It appears as a widespread rash of cratered sores and lasts one to two weeks. The infection can be fatal, however. Mortality is 12 percent in children under age five. Patients are treated in the hospital with the anitviral drug methisazine or vaccinia immune globulin and isolation from other susceptible family members. Patients with atopic dermatitis should be isolated from persons who have been vaccinated or who have herpes virus infections.

### VIII. OCCUPATIONAL DERMATITIS

Occupational dermatoses most commonly afflict homemakers (in the form of "housewife's eczema" of the hands), industrial workers and others with long exposure to water and strong cleaning agents or other chemicals. The structure of the skin breaks down and the skin becomes extremely sensitive to irritation. The eczema itself (Greek: ekzein, to boil out) produces itching, redness, blisters, scaling and skin fissuring. It comes and goes at the beginning, but becomes chronic as exposure to water and cleaners or other chemicals continues.

Once impaired, the structure of the skin is extremely slow in being restored. A 1972 study reported that 70 percent of 113 industrial workers still required treatment for it 10 to 13 years after they developed it.

Acute cases are treated with compresses of Burow's solution for 15 minutes three times daily, followed by application of potent steroid creams every two hours and under gloves during sleep. Patients should avoid rubbing or wetting their hands or exposing them to cleaners, wet diapers, bleached clothes, citrus juice and rinds, raw meats and vegetables, and other irritating substances. If the patient must handle these things, he or she should do so with rubber gloves, worn for brief periods only, and with steroid cream applied beforehand.

### IX. VENOUS STASIS DERMATITIS

Venous stasis dermatitis is associated with varicose (swollen) veins. Varicose veins occur in 10 percent of Americans and are associated with hereditary weakness of valves in veins that normally permit flow toward the heart and inhibit flow backwards. Contributing factors are pregnancy, obesity and a history of blood clots in the

The condition begins with accumulation of fluid in the ankle tissues and tan discoloration of the lower one third of the leg. It progresses to redness, and may be dry and scaling or oozing and blistered. In late stages, the skin is discolored red-brown, hard and deteriorated with fibrous scarring.

The condition is treated with a steroid cream four times daily and an elastic support in early, dry stages. In subacute, moist forms, compresses of Burow's solution for 15 minutes three times daily are followed with steroid cream. In addition to using the support bandage, the patient should lie down with the legs raised for 15 to 20 minutes three times daily. Severe spreading forms are treated with bed rest and compresses of Burow's solution followed by steroid cream, plus an antibiotic in case of infection.

Treatment of varicose veins is essential to prevent this dermatitis, because the skin condition is more easily prevented than treated.

### "Analysis Anonymous" Checks Illicit Drug Samples

As a pharmacist and recognized expert on drugs, you undoubtedly field occasional questions about drugs of abuse, including queries about the contents of unidentifiable drugs. In recent months, you may also have been asked about contamination of marijuana with paraquat, the defoliant being sprayed on marijuana crops by the Mexican government and which can cause respiratory toxicity. You can refer these kind of inquiries to a service of the Pharm Chem Research Foundation called "Analysis Anonymous."

To use the service, a sample (preferably the equivalent of one dose) should be carefully wrapped and sent with \$5 to: Analysis Anonymous, Pharm Chem Research Foundation, 1844 Bay Road, Palo Alto, CA 94303. "Hand Cancel" should be written on the envelope. To preserve anonymity, a 5-digit identification number (avoiding numbers like 12345 or 22222) should be included. This number may then be referred to when calling for results after 4-5 days — call (415) 322-9941. A written report will be sent if a return address is included. If possible, information should be included about alleged content of the sample, price, origin (city and state), and if any undesirable effects were associated with use.

### PA's "Read the Label" pamphlet now available

The Proprietary Association has announced the availability of its well-received "Read the Label" pamphlets.

The PA will make up to 100 of the pamphlets available to APhA members without charge. The pamphlets emphasize for patients — in straightforward language — the importance of reading labels on all medications before taking them.

To obtain your copies, write The Proprietary Association, Room 700-RTL, 1700 Pennsylvania Avenue, N.W., Washington, DC 20006.

### Dean Kinnard Receives Two Honors

Dr. William J. Kinnard, Jr., Dean of the School of Pharmacy of the University of Maryland, has been elected to the prestigious Institute of Medicine. He and Dean Jere E. Goyan, from the University of California School of Pharmacy, are the first pharmacy representatives to be elected to the Institute.

The Institute of Medicine was chartered by the National Academy of Sciences in the summer of 1970 to deal with problems associated with the delivery of adequate health services to all sectors of society — a goal that is increasingly viewed as a basic human right. In pursuit of this goal, the Institute conducts studies of policy issues related to health and medicine; issues position statements on these issues for public consideration; cooperates with the major scientific and professional societies in the field; identifies qualified individuals to serve on study groups in other NAS-NRC units; and disseminates information to the public and the relevant professions.

The American Association of Colleges of Pharmacy (AACP) recently honored Dr. Kinnard with the annual presentation of a Certificate of Appreciation. Dean Kinnard has just completed a three year term of association presidential offices. He had served previously on the AACP Board of Directors and as chairman of the Committee on Government Affairs.

Instrumental in the restructuring of the association, Dean Kinnard has been extremely active in bringing the concerns of pharmacy education to the attention of Congress and various federal agencies. Most recently he has been working with officials of the Food and Drug Administration (FDA) on the various proposals for drug regulation reform. He has advocated the expanded utilization of the pharmacist in FDA programs and has encouraged the agency to support a national center for clinical pharmacology and clinical pharmacy.

Dean Kinnard's tenure in the AACP offices began with a major reorganization of the association and the critical curriculum/degree (B.S. or Pharm.D.) discussions. He has studied the organizational structure and has called for added reforms. His speeches nationwide have called upon educators to make a competency-based approach to professional education. He has also reminded faculty that true academic strength can only be developed within the context of a strong research program.

A native of Pennsylvania, Dean Kinnard received his B.S. and M.S. degrees from the University of Pittsburgh. He was awarded the Ph.D. degree by Purdue University and then returned to Pittsburgh to serve on the faculty. He rose from the rank of instructor to professor while at Pittsburgh. He came to Baltimore in 1968 to assume the position of dean and professor of pharmacology and toxicology. He authored over 60 research publications in the areas of neuropharmacology, behavioral pharmacology, and cardiovascular pharmacology.

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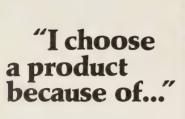
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### Joint Membership Requirements for MPhA/ APhA Suspended for 1979 Membership Year

In March, 1978 the APhA Board of Trustees took action which provided affiliated states the option of temporarily suspending the state/national reciprocal membership requirement for a period of up to 24 months from Setpember 30, 1978. The Board of Trustees of the MPhA determined that it would exercise that option, which becomes effective with the 1979 membership year.

PLEASE NOTE: In no way does the APhA or MPhA action diminish the dedication to unity within the profession which both associations have avowed as goals, and for which both have worked so tirelessly in the past. This action merely recognizes that unity within the profession does not rest exclusively on the reciprocal membership requirement.

Some of our more recent members may not be aware that the concept of mandatory reciprocal membership originated *not* with APhA, but with states that were seeking affiliation with APhA. This period of temporary suspension will provide the MPhA with an opportunity to determine whether the reciprocal membership requirement has a negative or a positive effect on its membership growth. It will also permit APhA to make similar evaluations.

While the situation may vary with individuals and from state to state, data recently collected by APhA indicates that almost all of our joint members understand and appreciate the necessity for supporting their local, state, and national professional associations. APhA data also suggests that, among the group who for economic reasons feel they must be selective, as many pharmacists will opt for national membership as will for state and/or local membership.

This action naturally would raise some questions about billing, dues payments, etc., for the period of temporary suspension. Some of the major questions appear below:

Question 1) Will I continue to receive separate renewal notices from my state association and from APhA for my professional association dues; and will I continue to send my state dues payments to MPhA, and my national dues payments to APhA in Washington?

Answer 1( Yes, in both instances.

Question 2) How will I indicate that I want to keep my membership in my state association and in my national association?

Answer 2) Merely return the invoice you receive from MPhA to us with your full state (and local) dues payment; and the invoice your receive from APhA to APhA with your full national dues payment. Each association will promptly credit your membership record, and your membership will be continued in each association.

Question 3) How will I indicate that I want state (and local) only or national-only membership during the temporary suspension period?

Answer 3) For the membership level you wish to continue, merely send your dues payment along with the invoice to that association. For the membership level you wish to discontinue, return that invoice with the notation: I DO NOT WISH TO CONTINUE THIS LEVEL OF MEMBERSHIP THIS YEAR. Following receipt of that advise, your professional associations will then make appropriate adjustments in your membership records.

Question 4) Will changing my membership affiliation during the temporary suspension period affect my membership after the temporary suspension period expires?

Answer 4) Your membership will probably not be affected because APhA and MPhA have historically followed the policy of not retroactively changing membership qualifications.

Over the years, and even more so in recent times, pharmacists in increasing numbers have expressed the desire for their professional associations to advance the concept of unity within the profession. Unity actually begins when individual pharmacists become and remain members at all levels (local/state/national) of their professional associations. So even though you will soon have the option of renewing your membership in MPhA-only or APhA-only, we hope you will personally help move the CONCEPT of unity within pharmacy one step closer to it becoming a REALITY by renewing your membership at all levels of your professional associations.

### **National PharmPAC Growing**

Washington, D.C. The political scene for pharmacists may change in the next few years in Washington because of the formation of a new Pharmacists' Political Action Committee. A group of pharmacists from several states and the District of Columbia have banded together to develop political support for pharmacists by raising funds to support candidates for Federal office who will support the pharmacists' goals.

The new political action committee is known as PharmPAC and it is chaired by pharmacist James B. Powers of Tallahassee, Florida. The treasurer is Richard D. Parker, the owner of a community pharmacy in the Washington, D.C. suburb of Kensington, Maryland. According to Parker, the idea to form a national PharmPAC that would appeal to all pharmacists originated with several pharmacists at about the same time. A few states have had political action committees for state elections a number of years and the pharmacists involved in these PACs were gradually becoming aware that the state effort alone was not enough to get results with certain drugand pharmacy-related issues.

Dick Parker, the immediate past president of the Maryland Pharmaceutical Association, said, "We saw there was interest in a national PharmPAC and we had just organized our state PAC, so we invited a group of pharmacists from several east coast states to meet with us to talk about forming a national committee. We met in Baltimore and met again in Washington about a year ago and decided to go ahead." As a result the PharmPAC has formed a temporary steering committee and is seeking additional participation for the committee from other states

Parker and Powers are particularly interested in finding pharmacists on the west coast and in mid-America and the South to serve on the steering commit-

Chairman Jim Powers, a Florida Pharmacy executive, says, "Strictly speaking, we are not a membership organization. One reason is that the co-founders of PharmPAC do not want to create another membership organization. They believe pharmacy already has enough national organizations and they want to see if

organizations to be heard in the Capital City." Powers and Parker recognize that pharmacy has many facits and that there may be many friends of pharmacy who want to help pharmacists achieve their political goals. They believe PharmPAC should appeal to all pharmacists, no matter where they practice, because it is designed to help preserve, protect and advance all pharmacists' interests.

Jim Powers says he agreed to chair the new political action committee because, "I want to help my profession make a real impact on health programs like National Health Insurance, Medicaid and Medicare Reimbursements, and the new drug legislation. More than anything," he says, "pharmacists need to be fairly paid for the services they perform when dispensing drugs. There should be no economic loss from participation in Federal programs."

Under Federal law governing political action committees, the chairman and treasurer must file papers giving certain data when the committee has collected or expects to collect at least \$1,000 in contributions. Then quarterly reports and other requirements must be complied with under the laws. PharmPAC has recently filed with the Federal Election Commission and has an arrangement with a political financial consultant to help with the re-

As treasurer, Dick Parker knows that what is needed now is money. He says, "We want to have as many large contributors as we can at this time, so we can effectively communicate with pharmacists across the land before the fall elections. Eventually we hope to hit our goal of \$2,000 per state or \$100,000 per year in contributions." Parker does not believe it will be easy, but he says, "With that kind of expenditure over the years we can make some inroads on the problems facing pharmacy in the Congress. This is less than \$1 per pharmacist per year," he points out, "so in the future we ought to be able to do much better." Most of the other health professions have PACs that raise more than \$100,000 per election.

Powers says the temporary steering committee is doing a good job of getting organized. "They have contributed dollars and time as well as expenses to attend several meetings. What we need now is for the pharmacists of the country to realize it is time to support our PharmPAC can make it easier for pharmacists in all \_efforts with their contributions," says Powers.

All contributions should be personal checks since corporate checks are not permitted under Federal law. The PharmPAC address is P.O. Box 23346, L'Enfant Plaza Station, Washington, D.C. 20024. Besides name and address, contributors should give occupation and place of employment to comply with the Federal reauirements.

The basic plan of PharmPAC is to support candidates for Federal office who are in general agreement with these objectives:

- (1) To protect, preserve and strengthen the American private enterprise system.
- (2) To protect, preserve and strengthen the profession of pharmacy so that its practitioners may render the best drug-related health care to those they serve without economic loss.
- (3) To prevent encroachment by government into the practice of pharmacy.
- (4) To permit pharmacists to render services for which they are better educated and trained than other health professionals and to charge appropriate fees for those services.

Other members of the steering committee are:

Bernard J. Cimino, a community pharmacist in Tampa, Florida.

James L. Creech, a community pharmacist in Smithfield, North Carolina. Mr. Creech was immediate past chairman of the North Carolina PharmPAC.

William R. Garland, a community pharmacist in Central Falls, Rhode Island, who believes strongly in getting a fair deal in Federal and state reimbursement programs.

Sharon Hobby, a hospital pharmacist in Atlanta, Georgia. Mrs. Hobby is a recent graduate of pharmacy and she wants to do her part to improve the profession.

Henry R. Peters, a hospital pharmacist in Washington D.C. A former member of the District of Columbia Board of Pharmacy, Mr. Peters has served as legislative chairman of the D.C. Pharmaceutical Association.

Paul A. Pumpian, a pharmacy executive in Cranford, New Jersey. Mr. Pumpian was formerly employed by the Food and Drug Administration and as secretary of the New Jersey and Wisconsin Boards of Pharmacy. William P. Schaffer, Jr., a community pharmacist in Edinburg, Indiana. Mr. Schaffer is a former member of the Indiana Board of Pharmacy and now serves as a County Commissioner.

Charles E. Thomas, a community pharmacist in Pittsburgh, Pennsylvania. Mr. Thomas has been active in pharmacy affairs for several years.

Stanley J. Yaffe, a community pharmacist in Baltimore, Maryland.

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For information regarding the programs write or phone:
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Sundays — 1:00 p.m. to 3:30 p.m. EXCEPT Cumberland Thursday — November 16, 1978, 9:30 p.m.,

Holiday Inn, Cumberland, Md.

December 3, 1978, Center of Adult Education, College Park, Md.

January 14, 1979, Biological Sciences Building, UMBC Campus

February 18, 1979, Sheraton Inn, Route 13, Salisbury, Md.

#### 6. March 4, 1979

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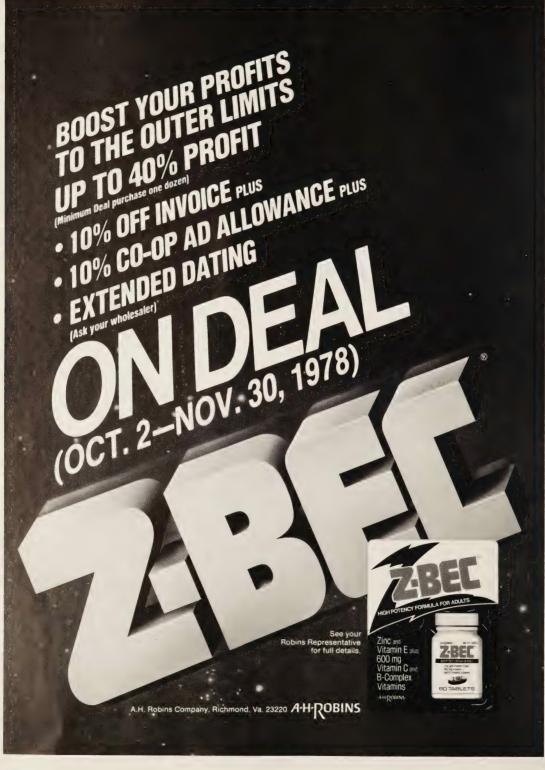
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### Is the Drug Product Selection Law in need of change?

by Estelle Cohen Public Commissioner Maryland Board of Pharmacy

Recently Commissioner Estelle Cohen was asked to investigate alternatives in an attempt to improve the drug product selection law which was enacted by the Maryland General Assembly last year.

This is her report to the Maryland Board of Pharmacy on this subject.

This week I came full circle in investigating the advisability of promoting a change in section 273 A(b) of the Maryland Drug Product Selection Law. The change would allow the pharmacist to charge his usual retail price for a generic drug.

To begin with, in August, I spoke with several independent pharmacists in Maryland who are actively engaged in substituting generic drugs for brand name drugs. Contrary to the chain store pharmacy representatives with whom I have spoken, none had strong reservations about the law as written, nevertheless, none would object to the change I proposed.

I also contacted people associated with pharmacy in Delaware, Florida and Wisconsin, states reported to have effective substitution laws. In Delaware, the pharmacist must communicate the cost savings to patients, and then pass them on to patients. The Florida law requires the pharmacist to pass on the full amount of savings realized by substitution. In Wisconsin, the pharmacist must charge a price at or below the wholesale cost of the brand name drug prescribed. They now have about 20% of prescriptions filled with generic drugs in Wisconsin. They have not done a study on savings to the consumer.

Next I spoke at length with Mr. Peter Holmes, an attorney who serves under Chairman Michael Pertchuck of the Federal Trade Commission. Mr. Holmes has been working on an extensive study being made by the FTC in conjunction with the Food and Drug Administration on aspects of the states substitution laws, as well as on the necessity of a federal substitution law. One objective of the research was to determine the type of provision in a substitution law that would most effectively encourage pharmacists to substitute low cost products. It is the opinion of Mr. Holmes and the members of the staff he heads, that it is the profit incentive that will operate to encourage pharmacists to dispense most readily. In October, 1978, Chairman Pertchuck and Chairman Donald Kennedy of FDA will release the staff recommendations to all states. One of the recommendations will be that the pharmacist charge the usual retail price for the generic drug. Another recommendation will be that federal legislation for a substitution law by postponed to allow time to observe the development and implementation of the substitution law in the various states.

This summer, Senator Bob Eckhardt, Democrat from Texas, of the House Sub-Committee on Consumer Protection and Banking, conducted hearings on HR1963, a federal drug product selection law. His research staffer has informed me that Senator Eckhardt and his committee have joined in the decision with Chairman Pertchuck and Kennedy to hold off on federal legislation on substitution at this time and for the same reason.

Some pharmacists utilize a professional fee system of pricing generically or otherwise in which the amount added to the drug cost is not related to the amount the pharmacist paid for the drug, while others use a percentage markup system of pricing in which the amount added does vary with the drug's cost to the pharmacy. The first method of pricing seems to create less difficulty for the pharmacist than the second method. A study of the effectiveness of drug product selection legislation in Delaware was made by two members of the Philadelphia College of Pharmacy and Science, Associate Professor Joseph L. Fink III and Associate Dean Maven J. Meyers. The study mentions that it and other studies have shown considerable price variation from pharmacy to pharmacy due to a number of factors including the systems of pricing as mentioned above, as well as the fact that the purchase of drugs can cost different amounts at different times depending on the quantity purchased or purchasing arrangements made with manufacturers and wholesalers. Also the services the pharmacist offers such as maintenance of patient profiles, patient consultation, delivery service, credit, product testing in pharmacy labs and the evaluation of generic suppliers, can increase operation costs and hence lead to higher prices. As the law now stands, it is very difficult if not impossible to enforce or to monitor the savings factor of substitution.

At a meeting of the Maryland Consumer Council held in the Attorney General's office, I had the opportunity to address leaders of various consumer groups in Maryland who were guests of the Council, to see if they felt the proposed change in the law could be supported by them at this point in time. I also broached a few Maryland legislators with the same question.

After discussion with the consumer representatives, I must report that the majority are not in favor of any change now, especially in light of the fact that our Maryland law has only been operative since April 78 and it has not been given the test of time. The two legislators also felt that it would be untimely to propose a change in the substitution law during the upcoming legislative session. The complexities involved in the change are not easily understood and however well motivated the call for change now may be, it is conceived as anti-consumer.

If the law is opened up for a change, there is the possibility that it would be amended similarly to the New York law requiring that the pharmacist dispense the cheapest product available. This would remove all professional judgement of quality and would not be in the best interest of the consumer.

Based on the above information, I must conclude that rather than promulgate change in the Maryland Drug Product Selection Law now, it would be more appropriate to evaluate the efficacy of the present law at the end of a year. If there are not significant savings for the consumer, Marylanders could then seek improvements in the law. Mr. Holmes has informed me that he and the FTC are available to work with the various states in effecting change in substitution laws or initiating them.

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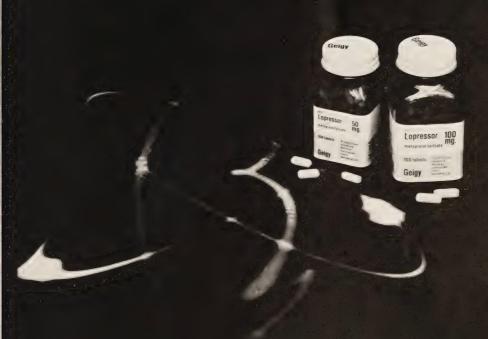
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In Patients Without a History of Cardiac Failure continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, patients should be fully digitalized and/or be given a diuretic, and the response observed closely. If cardiac failure continues, despite adequate digitalization and diuretic, Lopressor, brand of metoprolol tartrate therapy should be withdrawn.

Ischemic Heart Disease: Following abrupt cessation of therapy with certain beta-blocking agents, exacerbations of angina pectoris and, in some cases, myocardial infarction have been reported. Even in the absence of overt angina pectoris, when discontinuing therapy, Lopressor, brand of metoprolol tartrate, should not be withdrawn abruptly, and patients should be cautioned against interruption of therapy without the physician's

Bronchospastic Diseases: PATIENTS WITH BRON-CHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Because of its relative beta, selectivity, however, Lopressor, brand of metoprolol tartrate, may be used with caution in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment. Since beta, selectivity is not absolute, a beta, -stimulating agent should be administered concomitantly and the lowest possible dose of metoprolol should be used. It may be prudent initially to administer metoprolol in three doses daily, instead of two, to avoid the higher plasma levels associated with the longer dosing interval. (See Dosage and Administration.)

Major Surgery: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the im paired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures

Metoprolol, like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g. dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in restarting and maintaining the heart beat has also been reported with beta blockers.

Diabetes Mellitus: Beta-adrenergic blockade may mask symptoms of hypoglycemia (e.g., tachycardia) and may potentiate insulin-induced hypoglycemia. Lopressor, brand of metoprolol tartrate, should therefore be used with caution in diabetic patients, especially those with labile diabetes

### The relatively selective beta blocker with b.i.d. dosage for hypertension

Thyrotoxicosis: Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta blockade which might precipitate a thyroid storm.

Precautions Impaired Hepatic or Renal Function: The drug should be used with caution in patients with impaired hepatic or renal function.

Drug Interactions: Catecholamine-depleting drugs (e.g., reserpine) may have an additive effect when given with beta-blocking agents. Patients treated with Lopressor, brand of metoprolol tartrate, plus a catecholamine depletor should therefore be closely observed for evidence of hypotension and/or marked bradycardia which may produce vertigo, syncope, or postural hypotension.

Long-Term Animal Studies: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In a one-year study in dogs there was no evidence of drug-induced toxicity at or below oral doses of 105 mg/kg per day. Two-year studies in rats at three oral dosage levels of up to 800 mg/kg per day did not indicate an increase in the development of spontaneously occurring benign or malignant neoplasms of any type. The only histologic changes which appeared to be drug-related were an increased incidence of generally mild focal accumulation of foamy macrophages in pulmonary alveoli and a slight increase in biliary hyperplasia. Neither finding represents symptoms of a known disease entity in man. In a 21-month study in mice at three oral dose levels of up to 750 mg/kg per day, benign lung tumors (small adenomas) occurred more frequently in female mice receiving the highest dose than in untreated control animals. There was no increase in malignant lung tumors or total (benign plus malignant) lung tumors. The overall incidence of tumors or malignant tumors was also unaffected by metoprolol administration

Usage in Pregnancy: Reproduction studies in animals did not reveal any evidence of impaired fertility or of teratogenic potential. There was evidence in the rat of increased postimplantation loss and decreased neonatal survival (threshold between 50 and 500 mg/ kg). Distribution studies in mice confirm exposure of the fetus when metoprolol is administered to the pregnant animal. There are no well-controlled studies in pregnant women. Lopressor, brand of metoprolol tartrate, should be used in pregnant women only when clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Since most drugs are excreted in human milk, nursing should not be undertaken by mothers receiving metoprolol

Usage in Children: Safety and effectiveness in children have not been established

Adverse Reactions Most adverse effects have been

Central Nervous System: Tiredness and dizziness have occurred in about 10 of 100 patients. Depression was reported in about 5 of 100 patients. Headache, nightmares, and insomnia have also been reported but drug relationship is not clear.

Cardiovascular: Shortness of breath and bradycardia have occurred in approximately 3 of 100 patients. Cold extremities, Raynaud's disease, palpitations and congestive heart failure have been reported. See Contraindications, Warnings, and Precautions.

Respiratory: Wheezing (bronchospasm) has been reported in less than 1 of 100 patients. See Warnings.

Gastrointestinal: Diarrhea has occurred in about 5 of 100 patients. Nausea, gastric pain, constipation, flatulence, and heartburn have been reported in 1 of 100 or Allergic: Pruritus has occurred in less than 1 of 100

Miscellaneous: Peyronie's disease has been reported in less than 1 of 100,000 patients.

The oculomucocutaneous syndrome associated with the beta blocker practolol has not been reported with Lopressor, brand of metoprolol tartrate, during investigational use and foreign marketing experience

Potential Adverse Effects: In addition, a variety of adverse effects not listed above have been reported with other beta-adrenergic blocking agents, and should be considered potential adverse effects of metoprolol.

Central Nervous System: Reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics

Cardiovascular: Intensification of AV block (see Contraindications).

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Allergic: Erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress

Miscellaneous: Reversible alopecia.

Clinical Laboratory Test Findings: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase

Dosage and Administration Dosage of Lopressor, brand of metoprolol tartrate, should be individualized The usual initial dose is 50 mg twice daily whether used alone or added to a diuretic. The dosage may be increased at weekly (or longer) intervals until optimum blood pressure reduction is achieved. In general, the maximum effect of any given dosage level will be apparent after one week of therapy. Usual maintenance dosage is approximately 100 mg twice a day, with a range of 100 to 450 mg per day. Dosages above 450 mg per day have not been studied. While twice-daily dosing is effective and can maintain a reduction in blood pressure throughout the day, some patients, especially when lower dosages are used, will experience a modest rise in blood pressure toward the end of the 12-hour dosing interval. This can be evaluated by measuring blood pressure near the end of the dosing interval to determine whether satisfactory control is being maintained throughout the day. If control is not adequate, a larger dose, or three times daily therapy, may achieve better control. Beta, selectivity diminishes as dosage of Lopressor, brand of metoprolol tartrate, is increased.

This drug should be stored at controlled room temperature and protected from moisture.

How Supplied Tablets of 50 mg (capsule-shaped, scored, light red, film-coated) and 100 mg (capsuleshaped, scored, light blue, film-coated) are supplied in bottles of 100 and 1,000 and Unit Dose Packages of 100.

Store at controlled room temperature and protect from 667290 (8/78) C78-38

Before prescribing or administering, please consult complete product information.

Manufactured by: CIBA-GEIGY Canada Ltd. Dorval, P.Q. Canada H9S1B1 Distributed by: GEIGY Pharmaceuticals Division of CIBA-GEIGY Corporation Ardsley, New York 10502

Geigy



As part of their orientation to the University of Maryland School of Pharmacy, incoming pharmacy students were given a tour of the Association headquarters in the Kelly Memorial Building.



The Association hosted a cookie and coke reception for the new pharmacy students as they had an opportunity to get to know one another in the B. Olive Cole Museum.



# Summer Pharmacy Events

Members of the Upper Bay Pharmaceutical Association ponder a point during a recent local association meeting.

Pictures courtesy of Paramount Photo Service



A belly dancer supplied the special entertainment at the Anne Arundel County Pharmaceutical Association's recent crab feast.



Members and friends of the Association dispatched a number of crustaceans in the course of the evening.

# Operating the Prescription Department at a Profit

BRUCE R. SIECKER, Ph.D., R.Ph.

Director Pharmacy Management Institute American Pharmaceutical Association

### Introduction

Anyone who operates a community pharmacy can appreciate the feeling that the world is getting more complicated and moving at an even faster pace. Over the past decade a myriad of government regulations have emerged that affect the practice of pharmacy. The reports are more complicated and the amount of paperwork is astounding. Yet, hardly a week passes without some governmental agency dreaming up something else for the pharmacist to read, fill out, and mail. The whole notion of organized drug programs has occupied the pharmacist's attention to an even greater extent than was ever imagined just ten years ago.

How totally the community pharmacist understands the fact that drug costs from the supplier are on a steep rise. Utilities, labor costs, social security matching taxes, and insurance expenses, have been on a steep climb with little relief in sight. In short, it is getting harder and harder to make a decent living in a community pharmacy practice. Pharmacists, however, have never been easy to defeat economically. With each passing crisis the strongest pharmacies seem to emerge to become even better operations. The edge in terms of professional survival seems to be an aggressive, innovative pharmacist. Aggressive in terms of practicing "enlightened selfdetermination" so that important issues will not be decided through passive abandonment! Innovative in terms of paying attention and considering new ways of doing things; new ways of thinking!

This thesis of economics survival applies specifically to the heart of the modern pharmacy...the prescription department. Instead of pretending and hoping that the prescription department is paying its own way, the aggressive, innovative pharmacist can determine how well... or how poorly... the prescription department is doing. In other words, the first step to "enlightened self-determination" is to find out what the situation is. Pharmacists must first know whether the prescription department is producing any profit. Only then can management action have any measurable effect.

Extensive research and development efforts into an

entirely different approach to a pharmacy's accounting and information system indicate that the answer to how well the prescription department is doing is within reach. That approach, called the Uniform Cost Accounting System for Pharmacy® or UCAS® for short, attacks the problems of inadequate information, and an inability to negotiate or substantiate reimbursement needs, directly. It rests upon the need for comprehensive and consistent economic information as a useful adjunct in keeping the pharmacy economically viable. To more fully appreciate this new proposal, however, requires a short review of a pharmacy's operating characteristics and a brief appraisal of common pharmacy record systems.

### **Pharmacy Operating Conditions**

Although pharmacists are aware of the special nature of pharmaceutical services, there is recognition also of economic imperatives. Pharmacies that do not recover the true cost of operation either fold or require subsidies to survive. Due to the opportunity cost of capital, pharmacies must return a profit on invested assets. The long-term objective of investing one's personal assets in a pharmacy practice is to earn a reasonable profit, while maintaining a sound financial position. Pharmacy owners recognize this need and wait in anticipation for the annual financial statements from the accountant.

All aspects of society recognize the need to return an income for capital investment. The federal government pays interest on treasury notes; local municipalities could not sell revenue bonds without some explicit recognition of the need for profit on investment. Any long-term social policy, or pharmacy management action, that ignores this imperative is doomed to economic failure. Because a pharmacy's pricing structure . . . or a drug insurance program's reimbursement scheme . . . to a large extent determines whether costs will be recovered. pharmacists must be aware at all times of the relationship between pricing decisions and pharmacy costs.

A second important characteristic of most pharmacies is the dual nature. To the patron, a pharmacy is a single entity. There is little distinction economically between the prescription department and the non-prescription areas of the pharmacy. Pharmacy clients do not realize that the cost density and product-service mix of these two vital segments of a pharmacy are dramatically different. The duality is blurred further when the

<sup>\*</sup>This article is reprinted with permission from the *Texas Pharmacy*.

patient "checks out" in the lobby. Antibiotic prescriptions are rung out on the same cash register with the bottle of cologne and tube of toothpaste.

The feeling that consumers may not perceive any economic demarcation between the prescription and non-prescription areas of the pharmacy is not unexpected. In fact, why should they? It is not unusual for a pharmacist to be tending the front counter; it is not unheard of for the cosmetic clerk to deliver a prescription. And, everyone knows that interns "work everywhere for everyone". The dual nature of a pharmacy is important to pharmacy managers, however, when attempts are made to decide prices relative to pharmacy department costs and long-term profit goals.

The third important feature of a pharmacy that helps to lay the groundwork for a new accounting approach is the difference between standard services and special orders. Standard services are defined as the normal, everyday products and services of a firm. In economic terms, standard services should recover both the variable and fixed costs of operation, as well as provide the firm's profits. Each prescription dispensed should yield a gross margin that helps to recover the variable costs of producing the prescription. Excess gross margin, that is gross margin which is up and above the variable cost, contributes to paying the overhead costs of the pharmacy. When enough prescriptions, cough syrup, toothpaste, and magazines have been sold as that the pharmacy's overhead is paid, the pharmacy begins to produce a profit.

Most firms also produce what are termed special orders. Such goods and services represent the unusual, extra business that the firm does not expect to receive on a day-to-day basis. A prescription from an out-of-town vacationer is a form of special order. A one-time order from the local school district for fifteen dozen elastic bandages is a special order. When Medicaid prescriptions first appeared, they were "add-on" orders that would not be expected on an everyday basis in the absence of a public drug program. The point of this distinction is simple: the pricing decision and cost recovery for special orders are quite different than for standard services. Standard services must be priced so as to recover variable and fixed costs, as well as produce a net profit at the end of the year. Special orders, on the other hand, may be priced with a greater degree of flexibility. So long as the gross margin for a special order exceeds the variable cost of producing that good, the pharmacy is better off economically because the "above variable cost" gross margin will help cover fixed costs more rapidly. Covering the overhead costs more quickly means that the pharmacy will produce net profit faster!

As an example, consider a pharmacy that dispenses 25,000 prescriptions annually. The pharmacy sells nothing else and faces an overhead or fixed cost of \$50,000 a year. The manager has determined the average variable cost to dispense each prescription is 70¢ and that the average gross margin per prescription represented by the pharmacy's pricing system is \$2.70 The difference between the average gross margin and the average variable

cost of dispensing is \$2.00, that is, \$2.70 less 70¢. The \$2.00 "excess" is known as the contribution margin in that it contributes to the overhead or fixed costs of the pharmacy. Given the \$50,000 or overhead, the pharmacy will have to dispense 25,000 prescriptions to reach its breakeven point. The proof of this conclusion is seen by dividing \$50,000 by \$2. In other words, the pharmacy is just breaking even at 25,000 prescriptions.

Now, suppose that the local Medicaid agency approaches this same pharmacist and offers to pay a reimbursement of \$2.00 for each public welfare prescription dispensed even though the pharmacy is not making any profit at a \$2.70 per prescription level. The question is whether this pharmacist should accept the offer. From an economic perspective and as a short-run decision, the answer is an emphatic yes. Assuming that the Medicaid prescriptions will represent 1,000 special orders, the pharmacy will be better off economically to accept the offer. One thousand extra prescriptions will yield (theoretically, at least) \$2,000 in added gross margin, e.g., \$2.00 per prescription x 1,000 prescriptions. The cost to produce the special orders will be 1,000 x 70¢ or \$700. The pharmacy, therefore, would produce a net profit of \$1,300 under this assumption. Not great, but, to a pharmacist who is facing no profit for the year, \$1,300 is better economically than zero.

The problem with this sort of reasoning occurs when special orders become standard business as is fast becoming the case with various public and private drug programs. When special orders become standard services, it is economic suicide to accept reimbursement over the long-run that fails to cover all fixed and variable costs and produce a proportionate net profit on all like goods. All standard services must bear a proportionate share of the pharmacy's true economic cost. In fact, federal laws expressly forbid different prices to different clients for like services. Unfortunately, standard services masquerading as special orders by not recovering a pro rata share of cost are a common condition throughout the country today. One only needs to examine the various Medicaid reimbursement schedules to see the point.

In order to do much about this condition, however, requires two important changes. The first is mostly a change in attitude. That change requires that a pharmacy manager view the pharmacy as being two distinct entities - the prescription department and the nonprescription department. To do this means that a concern for whether the pharmacy is producing any net profit will be superseded by an interest in whether the prescription department and the non-prescription areas are producing a return for investment risk. To make this change means that the pharmacy manager will no longer view the pharmacies in Figure 1 as identical. Granted, casual observation by even the most experienced pharmacist most likely would discern the obvious differences in the three pharmacies that are represented. Yet, what pharmacy can produce an income statement that is specific for each major department segment of the pharmacy and, which follows the income equation from sales, through cost of goods sold, gross margin, expenses, and finally to bottom line? The answer: not very many!

This observation leads to the second change that will support an active management of pharmacy's economic problems. That change is a new way of approaching a pharmacy's accounting system. In order to retrieve the numbers that are required to produce even the most basic information, such as that in Figure 1 (p. 25), requires a more aggressive economic recording system. It requires that the pharmacy's economic history recognize the dual nature of a pharmacy. It requires that information be available that allows the manager to assess the direct and indirect costs associated with the prescription department if informed decision-making is to prevail.

### Common Pharmacy Record Systems

The argument to restructure a pharmacy's bookeeping system may be viewed from an even more general perspective. The first observation highlights a pervasive attitude that is counterproductive to informed decision-making. That attitude is one that translates into "accounting as a necessary evil." To pharmacists trained to save all of mankind, filling out daily cash reports hardly seems an attractive use of professional skill. Thought devoted to restructuring a pharmacy's management accounting data system hardly seems possible when the prescription department is "knee deep in alligators."

The dilemma is worsened when one considers that accounting and pharmacy operations management have been dropped from or deemphasized in almost all pharmacy programs around the country. It is one thing to want to upgrade a pharmacy's accounting system. It is quite another matter to know how! Students today are not particularly interested in anything that is not "clinical" in nature. Mention of economics, prescription pricing, costs of operation, or worse yet, profit, in the undergraduate pharmacy classroom is tantamount to blasphemy in some quarters. As the drug insurance situation grows ever more serious, each new class of pharmacy practitioners becomes less able to cope with even the most rudimentary economic problems.

One must recognize, also, that most pharmacy accounting systems are designed to answer income tax questions. That is, the bookkeeping system is designed to allow the pharmacist to conform to various tax laws. It is not designed to answer management questions. The question of what does it cost to dispense a prescription is not pertinent to the income tax question. Hence, the accounting system, designed in response to tax law, does not address the question. The internal revenue service is not especially interested that "eighty-nine percent of total labor costs were consumed in prescription department activities." Further, the IRS does not view net profit from the prescription department as any less taxable than profits derived from a soda fountain, cosmetic bar, or greeting card department. So, the typical pharmacy's accounting system is designed to answer the basic question of whether the pharmacy as a whole produced any taxable income, not how various departments fared.

The present situation places the community pharmacist in a precarious situation. Informed decisions regarding regular pricing strategies for the prescription department, or attempts to document the need for higher drug program reimbursement fees, require data. Such information must be recorded and retrievable in such a way as to answer the necessary questions. Crude attempts to survey the "average cost to dispense" skirt the problem . . . or worse yet, may aggravate it by lulling the pharmacist into an unwarranted passiveness. Field surveys are analgous to measuring milliliters with a milligram scale. Surveys attempt to answer economic questions from data that were recorded for income tax purposes.

### An Intro-Pharmacy Performance Approach

Problems are not solved just because there are adequate facts and figures available. Managers and people solve problems! The probability of making a good . . . or hopefully, a "least worse" . . . decision is improved, however, if all parties have access to comprehensive and consistent information. Decisions where uncertainty is the prevailing condition are not conducive to pharmacy's, or society's, best interests. There is just too much at stake to rely on "gut feel" forever. Pharmacy managers need better information.

To solve a complex problem well requires that all aspects of the situation be addressed simultaneously. In viewing the need for better economic information in a pharmacy, the following considerations were evident:

- (1) Prescriptions department and other department costs and profit figures are necessary to support informed management decisions.
- (2) Any record system should record all costs in a comprehensive manner.
- (3) Pharmacists have neither the skill nor time to design a new recording procedure individually.
- (4) Recording procedures should be uniform across all pharmacies so data validity is not in question.
- (5) The natural result of a pharmacy's accounting system should allow for compliance of income tax law yet at the same time produce management information that is useful to the pharmacy.
- (6) The system should be as simple to use as possible, given a complete recording of all necessary numbers.
- (7) The adopting pharmacy should not have to rely on outside help in order to employ the new accounting system.
- (8) Complete user manuals, that not only explain the system in detail but can be used also to orient new pharmacist graduates, are required.
- (9) The adoption of the system should not jeopardize the pharmacy's right to self-determination in terms of reporting information to outside parties.
- (10) Adoption of any new system should be on a voluntary basis.
- (11) Adoption costs should be minimized where possible.

# Liability Protection (It comes with every tablet you dispense)

A recent article on pharmacy law stated that "it is not unlikely that pharmacists substituting therapeutically or bioequivalent drugs for those prescribed will face increasing confrontation in the courts on the issue of their liability for unanticipated or ad-

verse reactions from drugs dispensed by them"\*

It should be reassuring to know, therefore, that McNeil Laboratories stands behind you every time that you fill a prescription for TYLENOL® with Codeine tablets or elixir—and, for that matter, for every McNeil product you dispense. The "McNeil Pharmacist Protection Policy" gives you this assurance. (If you don't already have a

copy, you might like to send for one.)

With the many problems facing the pharmacist today, why risk unnecessary liability problems.

\*From a special report reprinted from U.S. Pharmacist 2(4):18-23, 1977: "Pharmacy Law," by Michael R Sonnenreich, J.D.

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(12) The accounting system should not mandate any particular type of pricing system, nor pricing response, to costs that are identified by it.

(13) Above all else, the entire development should be tested thoroughly and deployed cautiously.

Today, there exists a set of accounting procedures that will do exactly what is required. Yet, it has undergone the extensive development that is described above. Called the Uniform Cost Accounting System for Pharmacy<sup>©</sup>, or UCAS<sup>©</sup> for short, the set of principles and procedures is being readied for final testing and distribution. Extensive development, testing, evaluation, and redesign efforts have been done. A rigorous set of user manuals, written in a "cookbook" or "How to" style, is complete. Publication plans by the American Pharmaceutical Association, which has led the way in supporting the development of UCAS<sup>©</sup>, are nearing completion. A final test of the system to make absolutely sure that it will work smoothly and perform as desired in a community pharmacy is planned by the American Pharmaceutical Association. In all, UCAS® represents a useful and innovative development for the community pharmacist. But more than that, it represents an opportunity to replace economic uncertainty with economic reality. It does not make management decisions for the pharmacist, but it certainly provides a solid data base from which to begin the process. It will provide indisputable evidence of pharmacy costs and give the community pharmacist an invaluable tool that has been lacking for some time.

#### Summary

The operation of a community pharmacy is surely no place for the weak of spirit. There are real problems to solve, and the world seems to get more complicated each day. Economic survival is certainly not assured. Few can afford to ignore the economic imperative that long-term pricing and reimbursement decisions must cover all costs of operation and provide a reasonable risk return if enough capital is to remain invested in the community pharmacy sector to serve the nation's needs. Good decision-making is enhanced when adequate information is available. Today's pharmacy accounting systems are designed to answer the income tax question, not the question of prescription department costs. Operating the prescription department at a profit presupposes some means of measuring departmental performance.

A voluntary solution to the need for improved departmental accounting information in a pharmacy is the Uniform Cost Accounting System for Pharmacy. It has been designed to solve as many aspects of the problem as are humanly possible. USAS does encourage that pharmacists undertake a more vigorous approach to pharmacy cost-finding. On the other hand, it rejects the notion that good decisions can be made consistently over a sustained period of time without adequate information about pharmacy departmental cost behavior. In the end, it is still up to the community pharmacist to discern what "enlightened self-interest" is all about.

NOTE: The terms "Uniform Cost Accounting System for Pharmacy®" and "UCAS®" are copyrights of the American Pharmaceutical Association, 2215 Constitution Avenue, N.W., Washington, D.C. 20037. All rights reserved.

FIGURE 1: A CO	OMPARISON OF THREE EQUALLY PROFITABLE PHA	RMACIES
Pharmacy "A":	Rx Net Profit Non-Rx Net Profit Total Net Profit	\$ 5,000 5,000 \$10,000
Pharmacy "B"	Rx Net Profit Non-Rx Net Loss Total Net Profit	\$15,000 (5,000) \$10,000
Pharmacy "C":	Rx Net Loss Non-Rx Net Loss Total Net Profit	\$(5,000) 15,000 \$10,000

### **IC Helps Maryland Pharmacists**

There are more than 40 members of the Maryland Pharmaceutical Association enrolled in the collection service provided by I.C. System, Inc. These members have recovered thousands of dollars in past-due accounts. In Frederick, a member recovered \$4,059. In Phoenix, one member collected \$2,477 and one in Federalsburg got back \$2,193. An Ellicott City member recovered \$2,060 and one in Oakland collected \$1,780.

From all over the area members are reporting favorable results and enrollments are on the increase. One reason for this is the localized coverage provided by company representatives. The Regional Office is managed by Don Dortch who has two representatives living in and working out of communities throughout the state. Each has an exclusive territory in which he must answer for enrollments, quality of service and has a direct inter-

est in collection effectiveness.

Nationally, the company collected an all-time record of \$22.6 million in 1977. A total of 48 pharmaceutical associations across the country now endorse the service for their members — and for good reason.

Service is personalized, localized and effective. Collections are guaranteed to return at least eight times the initial cost of the service. At the same time, you, the creditor, retain full control and are the only one who can make adjustments, accept partial payments or even forgive a debt entirely if such course of action seems appropriate.

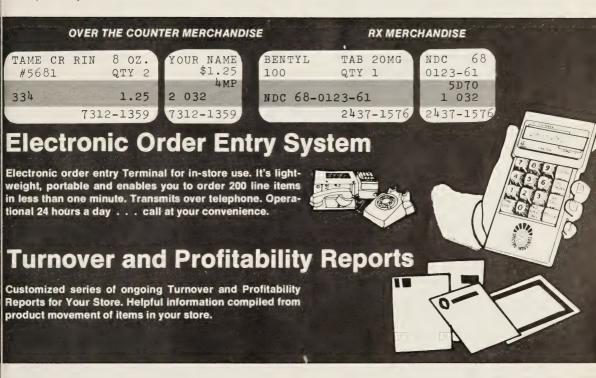
Should a question arise, you can phone the company's National Information Center on a toll free hot line. Customer service specialists are on hand to take calls Monday through Friday. And if they can't handle your problem, they will see that your local representative gets out to see you just as soon as possible.

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- · Price Stickers for Selected Full Cases.
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### SAPhA first meeting is successful

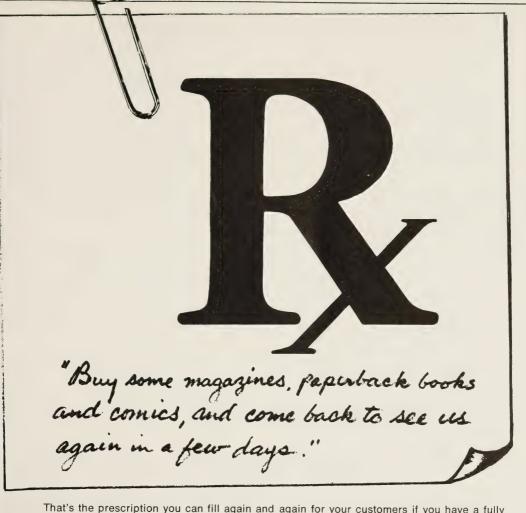


The first organizational meeting for the Maryland Student American Pharmaceutical Association was presided over by Ruth Sammel Blatt.

Pictures courtesy of Paramount Photo Service



The outstanding attendance at the meeting and the new programs planned by SAPhA indicates that this will be a successful year for the student organization.



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# **National Health Observances**

Published by the Hyatt Medical Enterprises Inc.

### Introduction

National Observances have become a tradition in the United States. Many of these are associated with health care and can be adapted to your community health education efforts.

A good example of an observance related to health care is National Hospital Week. Established as National Hospital Day in 1921 by the American Hospital Association to draw public attention to the work of hospitals, this event was expanded in 1953 to National Hospital Week. It is interesting to note that this special week always includes May 12, the anniversary of the birth of Florence Nightingale, whose efforts led to the improvement of the hospital systems in both the United States and England.

Events such as National Hospital Week offer interesting themes for health screenings, seminars, career days and tours of health care facilities. In many cases promotional material such s news releases, broadcast announcements, flyers, pamphlets, brochures, bumper stickers and even billboard signs are available from the agencies sponsoring the observances.

The following list briefly describes some of the more common days, weeks and months associated with health education and disease prevention. This compilation is not presented as a totally comprehensive catalogue of annual events of special interest to health care professionals. Rather, it is designed to assist you in expanding your role as a health educator by taking an active part in such health-related events.

Calendar

JANUARY ......Entire Month

# MARCH OF DIMES BIRTH DEFECTS PREVENTION MONTH

Background: By joint resolution Congress authorized and requested that the President annually designate the month of January as March of Dimes Birth Defects Prevention Month. (Public Law 93-561, December 30, 1974). For information: Contact your local March of Dimes chapter.

JANUARY .....Second Week

# NATIONAL EDUCATION WEEK ON SMOKING

Background: This program is designed to alert Americans — especially youths — to the dangers of smoking. For information: National Interagency Council on Smoking & Health, 419 Park Ave. S., New York, NY 10016.

FEBRUARY ......Entire Month
AMERICAN HEART MONTH

**Background:** Each year since 1964 Presidential proclamation has designated February as the month to emphasize health activities relating to the heart. (Public Law 88-254, December 30, 1963).

For information: Contact your local chapter of the American Heart Association.

FEBRUARY .....Second Week

# NATIONAL CHILDREN'S DENTAL HEALTH WEEK

**Background:** Founded by the American Dental Association to promote the prevention of dental disease through education.

**For information:** Bureau of Dental Health Education, 211 E. Chicago Ave., Chicago, IL. 60611.

# MARCH ......Entire Month RED CROSS MONTH

**Background:** By annual Presidential proclamation March is designated as the month to promote the goals and objectives of the American Red Cross.

For information: Contact the American National Red Cross, 17th and D Sts., N.W., Washington D.C. 20006.

MARCH.....Entire Month

# SHAMROCKS AGAINST DYSTROPHY

**Background:** A special drive to enlist high school and college youth's support for programs of research and patient care for victims of neuromuscualr diseases.

For information: Muscular Dystrophy Association, Inc., 810 7th Ave., New York, NY 10019.

MARCH ......Entire Month and
First Week in April

### EASTER SEAL CAMPAIGN

**Background:** An annual appeal to the public for support of Easter Seal Society's services to some 300,000 crippled children and adults.

For information: Public Relations Director, National Easter Seal Society, 2023 W. Ogeden Ave., Chicago, IL 60612

MARCH .....Second Week

### SAVE YOUR VISION WEEK

**Background;** By Presidential proclamation the second week in March is designated to help remind Americans to appreciate and protect their vision.

For information: American Optometric Association, 7000 Chippewa St., St. Louis, MO 63119

MARCH......Third Week

NATIONAL POISON
PREVENTION WEEK

**Background:** By annual Presidential proclamation (Public Law 87-319, September 26, 1961) this week encourages Americans to learn the dangers of accidental poisoning and to take preventative measures.

**For information:** National Planning Council for Poison Prevention Week, P.O. Box 1543, Washington, D.C., 20013

# MARCH......Third Week COMMUNITY HEALTH WEEK

**Background:** Proclaimed annually since 1944 by the California State Legislature as a week for special programs, projects and events related to community health. **For information:** Contact Ruth Temple, M.D., 601 South Orange Grove Ave., Pasadena, CA 91105

## MARCH 27:

# BIRTHDATE OF WILHELM ROENTGEN

**Background:** Born in 1845, this German scientist discovered x-rays.

### MARCH 30:

### DOCTOR'S DAY

**Background:** This annual event originated in 1842 in Athens, Georgia. The first Doctor's Day, was declared in recognition of one of the initial successful medical operations utilizing anesthesia. In 1935 the state of Georgia officially recognized the day; the tradition of presenting red carnations to physicians was adopted in 1949. In 1958 the United States Congress officially designated this day to recognize the dedicated, devoted service of doctors.

# APRIL .......Entire Month CANCER CONTROL MONTH

**Background:** By Presidential proclamation (Public Resolution No. 82, March 28, 1938) April is especially designated to educate Americans about the causes and controls of cancer. During April the American Cancer Society intensifies its year-round education program and launches a fund-raising campaign to conquer cancer.

For information: Contact your area chapter of the American Cancer Society.

### APRIL 5:

# BIRTHDATE OF SIR JOSEPH LISTER

**Background:** This English physician, born in 1827, was the founder of antiseptic surgery.

### APRIL 7:

# WORLD HEALTH DAY

**Background:** Commemorates the establishment of the World Health Organization on April 7, 1948. Each year a featured theme is selected to help promote good health on an international level.

For information: Public Information Office, World Health Organization, 525 23rd Street, N.W., Washington, D.C.

APRIL.....Second Week

# NATIONAL MEDICAL LABORATORY WEEK

**Background:** This special week recognizes the valuable contribution of laboratory personnel to modern-day health care.

For information: American Society of Clinical Pathologists

# APRIL .....Last Week SECRETARIES WEEK

**Background:** Established to acknowledge the contributions of secretaries to the vital roles of health care business, education and government.

For information: Contact the National Secretaries Association, 2440 Pershing Rd., Suite G-10, Kansas City, MO 64108

# APRIL ...... Last Week NATIONAL VOLUNTEER WEEK

**Background:** A special week to honor volunteers and voluntary groups such as hospital auxiliaries.

For information: Contact the National Center for Voluntary Action, 1785 Massachusetts Ave., N.W., Washington, D.C.

# 

**Background:** Founded by the National Association for Mental Health to emphasize its goal of good mental health and expanded treatment servics. During this week, especially, programs are presented to educate the public about mental illness.

For information: Contact the Communications Department, National Association for Mental Health, 1800 N. Kent St., Arlington, VA. 22209.

# MAY ......Entire Month NATIONAL

# ARTHRITIS MONTH

**Background:** This month helps draw attention to the need for additional research to find the causes and cure for arthritis

**For information:** The Arthritis Foundation, 475 Riverside Drive, New York, NY 10027

33

OCTOBER, 1978

MAY .....Entire Month

# NATIONAL HIGH BLOOD PRESSURE MONTH

**Background:** Founded by the Department of Health, Education and Welfare, this month serves as a target time to intensify the development of community-based hypertension control programs as well as to focus national attention on the dangers and extent of high blood pressure.

For information: Contact the High Blood Pressure Information Center, 120/86 National Institutes of Health, Bethesda. MD 20014

MAY .....Entire Month

# BETTER HEARING AND SPEECH MONTH

**Background:** Throughout this month a public education program is presented to encourage early awareness of problems related to hearing and speech.

For information: American Speech and Hearing Association, 9030 Old Georgetown Rd., Washington, D.C. 20014

**MAY 8:** 

### WORLD RED CROSS DAY

**Background:** Established to honor Henri Durant, originator of the Red Cross as an international humanitarian movement.

For information: Contact the American National Red Cross, 17th & D Sts., N.W., Washington, D.C. 20006

MAY 12:

# BIRTHDATE OF FLORENCE NIGHTINGALE also INTERNATIONAL NURSES DAY

**Background:** Born in 1820, this English nurse — noted for her heroics during the Crimean War — is regarded as the founder of modern nursing. On this day nurses throughout the world are honored.

For information: International Council of Nurses, Box 42, CH1211 Geneva 20, Switzerland

MAY.....Second Week

### NATIONAL HOSPITAL WEEK

Background: Founded to focus attention on hospital's contributions to the good health of their communities, this week helps to inform the public about the growing challenges and responsibilities faced by health care institutions.

For information: Contact the American Hospital Association, 840 N. Lake Shore Drive, Chicago, IL 60611

MAY.....Second Week

# NATIONAL NURSING HOME WEEK

**lackground:** The purpose of this week is to increase ommunity awareness of the services offered by long erm health care facilities.

For information: Contact the American Health Care Association, Dept. of Public Affairs, 1200 15th St., N.W., Washington, D.C. 20005.

MAY...... Second Week
FOOT HEALTH WEEK

**Background:** Sponsored by the American Podiatry Association, this week promotes the proper care and treat-

sociation, this week promotes the proper care and treatment of your feet.

For information: American Podiatry Association, 20

PUBLIC RELATIONS WEEK

**Background:** This week honors public relations and publicity workers for their professional services.

For information: Contact Richard R. Falk Associates, 220 W. 42nd St., New York, NY 10036

AUGUST ...... Entire Month
GOOD NUTRITION MONTH

**Background:** This was established to make Americans conscious of the variety of foods available in the U.S. and the ways to use them wisely and well.

For informatioon: Contact the Gourment Club, 3369 Hamilton Way, Los Angeles, CA 90026

**AUGUST 6:** 

# BIRTHDATE OF SIR ALEXANDER FLEMING

**Background:** The British bacteriologist, born in 1881, who discovered penicillin. He was awarded the Nobel prize for medicine in 1945.

### SEPTEMBER 17:

### EXPECTANT FATHER'S DAY

**Background:** This special day honors expectant fathers. **For information:** Expectant Father's Association, P.O. Box 1414, Hollywood, FL 33022

OCTOBER.....Entire Month

# IMMUNIZATION ACTION MONTH

**Background:** This special month stemmed from the finding that immunization levels in young children were declining. It was established to increase immunizations against polio, measles, mumps, diptheria, pertussis and tetanus.

**For information:** Contact the Center for Disease Control, Immunization Division B. SS., Atlanta, GA 30333

OCTOBER.....First Monday

### CHILD HEALTH DAY

**Background:** Declared by Presidential proclamation, this day stresses the need for ongoing attention to child health care. Occurring in October, the observance of Child Health Day has become closely allied with Immunization Action Month in recent years.

**For information:** American Academy of Pediatrics, P.O. Box 1034, Evanston, IL 60204

### OCTOBER 13:

# BIRTHDATE OF RUDLOPH VIRCHOW

**Background:** German pathologist, anthropologist and statesman, born in 1821, considered to be the Father of Pathology.

OCTOBER .....Second Week

# NATIONAL FIRE PREVENTION WEEK

**Background:** This week, designated by Presidential proclamation, serves to remind people to use fire-safe practices all year round.

**For information:** Contact the National Fire Protection Association, 470 Atlantic Ave., Boston, MA 02210

### OCTOBER 15:

### WHITE CANE SAFETY WEEK

**Background:** A day devoted to safety for blind persons. Established by proclamation (Public Law 88-628, October 6, 1964).

For information: Contact the United States Dept of Health, Education and Welfare.

OCTOBER.....Third Week

# DRUG ABUSE PREVENTION WEEK

**Background:** Held annually by Presidential proclamation, this week serves to alert all segments of the public to the continuing problems of drug abuse.

**For information:** National Institute on Drug Abuse Clearinghouse, 11400 Rockville Pike, Rockville, MD 20852

NOVEMBER-

DECEMBER ......Entire Month

# CHRISTMAS SEAL CAMPAIGN

**Background:** This is a fundraising campaign to support the fight against emphysema, tuberculosis, chronic bronchitis, smoking and air pollution in the United States.

For information: Contact the Public Relations Director of the American Lung Association, 1740 Broadway, New York, NY 10010

NOVEMBER-

DECEMBER ..... Entire Month

# NATIONAL DIABETES MONTH

**Background:** The objectives of this month are threefold—to detect the undiagnosed diabetic, to increase public awareness of the disease and recognition of warning signs, and to raise funds for research towards a cure and prevention

For information: Contact your local Diabetes Association affiliate or the American Diabetes Association, 600 fifth Ave., New York, NY 10020

NOVEMBER ..... Entire Month

# MENTAL RETARDATION MONTH

**Background:** This month was initiated to draw national attention to the problems and potential of mentally retarded individuals. Each year the campaign is focused around a particular theme.

For information: National Association for Retarded Citizens, 2709 Avenue E East, Arlington, TX 76011

# NOVEMBER ......Second Week MEALS ON WHEELS WEEK

**Background:** This week acknowledges a service to homebound elderly persons compatible with the philosophy of the President's Council on Nutrition.

For information: Contact the Public Information Officer of the Eau Claire Area Public Schools, 122 Mappa St., Eau Claire, WI 54701

# **DECEMBER 24:**

# BIRTHDATE OF BENJAMIN RUSH

**Background:** This legendary physician of the American Revolution was born in Byberry, PA, in 1745.

### DECEMBER 27:

# BIRTHDATE OF LOUIS PASTEUR

**Background:** The French bacteriologist, born in 1822, who discovered the innoculation against rabies. The pasteurization process to check fermentation of fluids is named for him.





OCT. 16-24 — MPhA MONTE CARLO TRIP. GOOD LUCK AT THE CASINO.

OCT. 19 — Anne Arundel Co. Assn. Meeting — Empire Towers 6:30 p.m.

OCT. 18 — Upper Bay Assn. Meeting — Flying Clipper 9:30 p.m.

OCT. 26 — MPhA FALL REGIONAL MEETING — Holiday Inn BWI

OCT. 29 — Alumni Association Oyster Roast

NOV. 2 — BMPA Annual Meeting and Election of Officers

NOV. 5 — PG/MC Pharm. Assn. — Installation Banquet

NOV. 9 — MSHP Special Fall Seminar

JAN. 14-22 — WINTER TRIP TO ST. MAARTEN

— RESERVE NOW TO ASSURE SPACE! FEB. 11 — BMPA Installation Banquet — Bluecrest

MARCH 4 — SWAIN SEMINAR

OCTOBER, 1978

With more than 10 million chlordiazepoxide HCl scripts per year...

# Why do the overwhelming majority of physicians specify Librium? (chlordiazepoxide HCI)

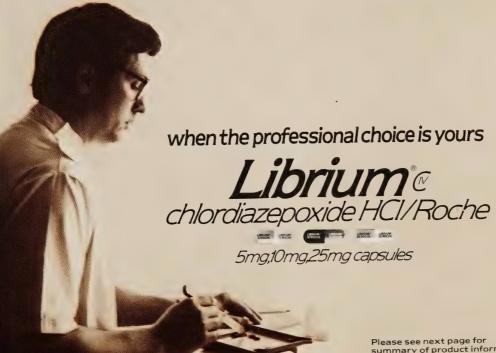
- Proven performance within a wide safety margin
- □ Documented experience in actual clinical use
- Is used concomitantly with primary medications, such as anticholinergics and cardiovascular drugs.

The discovery of Librium by Hoffmann-La Roche represented a landmark in psychotherapeutics. Today, the confidence in Librium expressed by the medical community is based firmly on experience and a well documented clinical record. This is why the overwhelming majority of physicians continue to specify <u>Librium</u> when they prescribe chlordiazepoxide HCI.



# Why do the overwhelming majority of pharmacists dispense Librium? (chlordiazepoxide HCI)

- □ Proven antianxiety performance; unsurpassed safety record
- □ Faster turnover with the most widely prescribed brand
- □ Liberal Roche return goods policy
- □ Product liability protection program



summary of product information.

# Librium® 5mg,10mg,25mg chlordiazepoxide HCI/Roche

Please consult complete product information, a summary of which follows:

Indications: Relief of anxiety and tension occurring alone or accompanying various disease states. Efficacy beyond four months not established by systematic clinical studies. Periodic reassessment of therapy recommended

**Contraindications:** Patients with known hypersensitivity to the drug

Warnings: Warn patients that mental and/or physical abilities required for tasks such as driving or operating machinery may be impaired, as may be mental alertness in children, and that concomitant use with alcohol or CNS depressants may have an additive effect. Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions), following discontinuation of the drug and similar to those seen with barbiturates, have been reported

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (e.g., excitement, stimulation and acute rage) have been reported in psychiatric patients and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship has not been established

Adverse Reactions: Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin erruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction; changes in EEG patterns (low-voltage fast activity) may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making protracted therapy.

Usual Daily Dosage: Individualize for maximum beneficial effects. Oral—Adults: Mild and moderate anxiety and tension, 5 or 40 mg t.r.d. or q.i.d.; severe states, 20 or 25 mg t.i.d. or q.i.d. Seriatine patients: 5 mg b.i.d. to q.i.d. (See Precautions.)

Supplied: Librium\* (chlordiazepoxide HCl) Capsules, 5 mg, 10 ms and 25 mg—bottles of 100 and 500; Tel-E-Dose\* packages of 100. available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10; Prescription Paks of 50, available singly and in trays of 10. Libritabs\* (chlordiazepoxide) Tablets, 5 mg, 10 mg and 25 mg—bottles of 100 and 500. With respect to clinical activity, capsules and tablets are indistinguishable

ROCHE Roche Products Inc Manati, Puerto Rico 00701

# Lif-O-Gen units featured in Pharmacies

(from Southeastern Drug/Southern Pharmaceutical Journal)

How can you make your pharmacy the "health care center" in your community?

We can report that one good way is to stock and feature such items as the Lif-O-Gen home emergency oxygen unit — so very important for people who may be suffering from emphysema, asthma attacks, heart or circulatory disease.

For instance, Lif-O-Gen's portable, lightweight unit, Model 500, is simple to operate and is especially valuable for emergency use. When seconds count, the Lif-O-Gen unit can mean a vital difference until professional medical help takes over.

That's why pharmacists ought to feature it — and let their customers know about it.

In a recent interview, William J. Walsh, Lif-O-Gen's Marketing Manager, told us about a unique test program that the company has been conducting in the Pinellas County, Fla., area (on Florida's west coast, including St. Petersburg and environs). The campaign was designed specifically to increase public awareness of the Lif-O-Gen units in local drug stores, and to emphasize their economy and convenience.

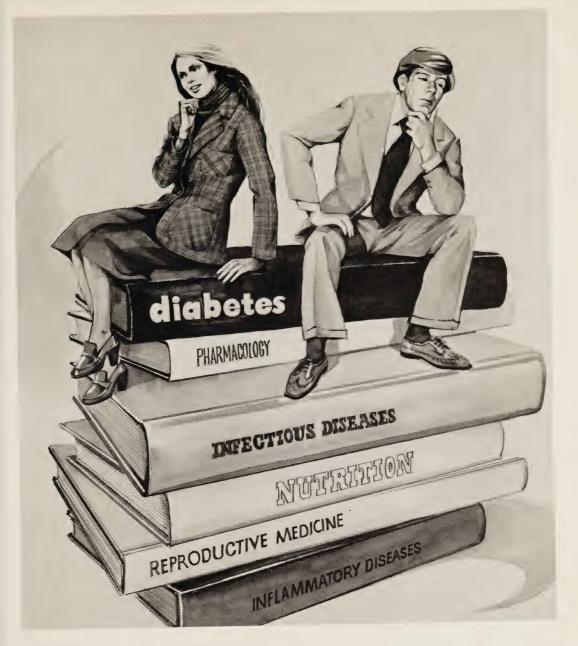
# Effective Campaign

Walsh said that the campaign is proving to be highly effective in every respect. All of the television commercials and newspaper ads included the phrase that the Lif-O-Gen products were "available at your local pharmacy," and many have reported additional sales and favorable reaction from patients.

Actually, most communities of any size today include people who have the problems of emphysema, or asthma, or who may be ailing with heart or circulatory disease. The pharmacy can render a valuable and most-appreciated service by catering to their needs throughout the year.

Lif-O-Gen is recognized as one of the leading manufacturers in the U.S.A. of portable oxygen units, specialty gases and all related hardware. To meet the everincreasing demands of millions of people, the company maintains large, modern facilities in Cambridge, Md., and Santa Ana, Calif. Engineers and technicians equipped with the latest analytical in-plant production equipment in the industry are working to produce the Lif-O-Gen products.

Accoring to Walsh, the rigorous production standards and commitment to quality have given Lif-O-Gen products a reputation for unmatched dependability and trustworthiness. "Pharmacists, physicians and other health professionals can recommend our products with assurance that they are offering the finest available," he said.



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stand the "how" and "why" of a product as well as the "what".

Which means, as a service to pharmacy, they can answer your questions correctly on a whole stack of subjects.



And that's the way we planned it.



( 1978 The Upjohn Company Kalamazoo Michigan

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# THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association

NOVEMBER, 1978 VOL. 54 NO. 11



Minoxidil ---

A New Investigational Hypotensive Agent

Local Association news in pictures

Hypertension in Childhood

# THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET BALTIMORE MARYLAND 21201 TELEPHONE 301/727-0746



NOVEMBER 1978

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# Manufacturers' Differential Pricing

For a long time now, pharmacists have had to play pricing games with various distributors of pharmaceuticals as a part of conducting business in the community retail pharmacy setting. No one would argue that there is not a place for incentives, deals and the recognition of volume purchasing. There are times, however, when these games become insulting to the practicing pharmacist.

What are we to make of the situation when a pharmacist can buy from a wholesale source at a less expensive price for the same product than from a direct purchase of the manufacturer? Clearly there are some abuses in this area. Pharmacists are made to feel that they are second class citizens in this scheme. The proper marketing procedures have been reduced to a shambles and we have been subjected to a veritable jungle of different prices and pricing mechanisms.

All of this, of course, has not escaped the attention of the organized consumer movement or our federal government. Now we are witnessing, in part, a reaction to these practices on the part of some manufacturers. Maybe the cure will be worse than the illness. But, perhaps we will eventually return to the day when we can all understand how a given product is marketed under pricing systems that make sense for all pharmacists, regardless of where they practice.

One of the solutions to this problem is for pharmacists to voice their dissatisfaction when they are confronted with this situation. Write to your manufacturers and let them know how you feel. Be sure to send a copy of the letter to the office.

Have Joy John



# — A New Investigational Hypotensive Agent

By Craig Svensson Pharmacy student

### INTRODUCTION

Hypertension is one of the nation's leading causes of death. Often called the "Silent Disease," its treatment is not simple. This is particularly true in cases where conventional therapy does not work. There is presently under investigation a new orally effective, potent hypotensive agent. That agent is 6-imino-1,2-dihydro-1hydroxy-2-imino-4-piperidinopyrimidine, or minoxidil. It has a chemical structure unlike that of any other antihypertensive agent and its action is that of a vasodilator. The purpose of this article is to familiarize the reader with the general principles and actions of the drug. This article may be of particular interest to the hospital pharmacist who may be dealing with the investigational drug or the community pharmacist who may have to field questions concerning the agent from investigational outpatients.

# PHARMACOLOGY

Minoxidil's hypotensive effect is manifested by its action on vascular smooth muscle, primarily at the arteriole level, to decrease peripheral resistance.<sup>1,2</sup> Significant sympathetic blockage or venous distension are not noted with minoxidil.¹ Due to the normal compensatory mechanisms of the human body, tachycardia and fluid retention are two major side effects. The first has been treated successfully with concomitant use of propranolol.<sup>1,3,4,5</sup> Fluid retention can be treated by restricted salt and fluid intake and/or concomitant therapy with hydrochlorothiazide or furosemide.<sup>1,3,5,6</sup>

Animal studies indicate that minoxidil may also impair peripheral adrenergic neuronal function.<sup>2</sup>

"Although peripheral adrenergic function is impaired by minoxidil, it is obvious that components of the sympathetic nervous system remain functional."

A desirable property of minoxidil is its lack of pharmacological effect on systems other than the cardiovascular system. CNS function was unaffected by doses of minoxidil up to 100 mg/kg.<sup>2</sup>

"No antidiabetic, antifertility or anti-inflammatory activity was demonstrable. It failed to antagonize anaphylatic shock and exhibited no antibacterial, antifungal, antiviral, or antineoplastic activities. It also lacked significant effects on serum lipd levels." 2

Toxicologic studies indicated that minoxidil was nontoxic to laboratory animals at doses far exceeding those necessary for hypotensive activity. It was found to be non-teratogenic in rats and rabbits.

# CLINICAL STUDIES

In one study involving 100 patients with a mean pressure of 212/125 mmHg, treatment with minoxidil reduced the mean pressures to 151/91 mmHg. 6 After therapy, 94 per cent of the patients had a supine diastolic pressure less than 100 mmHg within 4 weeks. Diuretic therapy was necessary in all but one patient. 6

Dunea et al, express the opinion that the use of minoxidil may prevent the necessity for nephrectomy in patients unresponsive to other treatments.<sup>3</sup> They found that in such a patient renal function improves. One dialysis patient in their study improved to the extent that dialysis could be discontinued.

Mutterperlet al, found minoxidil to be effective in the treatment of malignant hypertension associated with chronic renal insufficiency. 8 Commenting on a study involving the management of severe childhood hypertension with minoxidil, Sinaiko and Mirkin stated,

"The vasodilating agent minoxidil when used in combination with propranolol and hydrochlorothiazide offers an important adjunct to current antihypertensive therapy for severe, refractory hypertension in children. The potential benefit of minoxidil in obviating the need for prolonged hospitalizations and providing an alternative to nephrectomy in patients with seriously compromised renal function leads us to believe that further trials with this drug are warranted within the pediatric population of hypertensive patients "5"

In a double-blind comparison of minoxidil and hydralazine, minoxidil was found to have better long term control. Another study involving patients with severe to moderate hypertension found that minoxidil was superior to hydralazine. These researchers indicated that with minoxidil blood pressure was controlled earlier and more easily — with less side effects. 3

# MINOXIDIL-INDUCED HYPERTRICHOSIS

The most often occurring side effect is hypertrichosis, excessive growth of hair. The excessive hair growth is most prevalent in the facial area. However the arms and legs may also be involved. Thickening and darkening of hair may also occur. <sup>10</sup> The cause of this is not known. The side effect is most disagreeable in female patients. In some studies female patients withdrew from the study due to the development of hypertrichosis.

Earhart et al., have suggested the use of a calcium thoglycolate depilatory for the treatment of minoxidil-induced hypertrichosis. <sup>10</sup> In their study five (5) female patients with minoxidil-induced hypertrichosis used a calcium thioglycolate depilatory (Surgex). <sup>10</sup> The patients were first tested for possible sensitivity to the cream and then the areas of hypertrichosis were treated.

"All five women achieved complete removal of the unwanted hair with minimal or no skin irritation and showed tremendous enthusiasm over the excellent cosmetic result." 10

The authors expressed the opinion that while barium sulfide is more effective in removing hair, it is also more irritating to the skin than calcium thioglycolate. This calcium thioglycolate was chosen as the depilatory of choice.

### COMMENT

Minoxidil may prove to be a valuable addition to the list of those agents available for the treatment of hypertension. It may prove invaluable in treating those with severe hypertension who would otherwise have to undergo nephrectomy. While more clinical studies are needed, and several are presently going on, the future of minoxidil is promising.

NOTE: Minoxidil is manufactured by Upjohn. A trade name for minoxidil has yet to be assigned.

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# **USP DRUG PRODUCT PROBLEMS REPORT\***

by the USP Convention, Inc.

12601 Twinbrook Parkway, Rockville, MD 20852 Tel. (301) 881-0666

### Name Game

Several reports from pharmacists around the country pointed out that the same brand name was being used for three different dosage forms of a product and that the dosage forms contained different active ingredients. The ingredient in the liquid dosage forms was aminophylline; but the solid dosage form contained theophylline. The reports indicated this caused confusion in converting from one form of the brand product to another, in generic prescribing and in product selection. A regulatory letter citing misbranding was issued by the FDA to the manufacturer.

## Hypertensive OTC

A Virginia community pharmacist became concerned about an OTC combination antacid-laxative-diuretic product that two of his hypertensive patients were taking. After carefully reading the label, he indicated on a DPPR that the medical claims were misleading and extremely dangerous. The FDA issued a regulatory letter to the manufacturer stating that the labeling was in violation of the Food, Drug, and Cosmetic Act.

### Antidote Anecdote

A North Carolina hospital pharmacist pulled a bottle from a case of a topical antiseptic solution for the infant umbilical area and found that it was labeled as syrup of ipecac. The label was apparently incorrect and the contents did appear to be the antiseptic. There was immediate concern that bottles of antiseptic labeled as ipecac would be used when ipecac was hurriedly needed in an emergency poisoning situation. The firm was unable to determine the extent of the mix-up and issued an urgent recall letter.

# Hypodermic Tablets Obsolete

The manufacturer of a narcotic analgesic discontinued the use of hypodermic tablets, but three years later was no longer specifying on the label that the tablets were "for oral use only." The new tablets contained inert fillers and dyes and were no longer to be used IM. A consultant pharmacist for a Texas hospital reported the hospital staff had been trying with difficulty to dissolve the tablets for IM use. The company notified the pharmacist and USP that the labels would be amended to state again "for oral use only."

## Neither Too Hot Nor Too Cold

The hard gelatinous precipitate in an aluminum magnesium suspension was reported by a Kansas pharmacist as being difficult to resuspend. An FDA inspection of the firm revealed that the storage of the product at temperatures too hot or too cold would cause the product to precipitate. The specific temperature range was not given on the label, only to "avoid freezing". The firm said it will include a more complete storage statement in the next label printing.

# Skid Halted

A pharmacist in a medical center pharmacy in North Carolina using 5ml vials of sodium chloride solution 0.9% found that although the vial labels and cartons of 100 correctly listed the volume, inner bags of ten vials incorrectly stated the contents as 3ml. At the firm the problem was traced to a mixed order of bags received from the printer which was not detected during normal inspections. The firm tightened incoming inspection procedures to assure that the bag printer did not mix different bags together on the same skid.

# Macro Number of Reports

Over a period of fifteen months, fourteen reports were received regarding precipitation and crystalization in two suspensions of theophylline. Exposure to temperature variations was causing macrocrystal formation which led to either sub-potency or super-potency. Storage at room temperature for several days and vigorous shaking was required to return the product to its original condition. The manufacturer had been cooperative in exchanging the merchandise, but recalled all lots of both products when the extent of the problem became apparent.

<sup>\*</sup>This report covers some of the recalls, product improvements, and explanations to which the Drug Product Problem Reporting Program has contributed. The product and company names are omitted; and no reflection on any specific manufacturer, distributor, reporter, or product is intended or should be inferred from the case studies. It is hoped that these examples will indicate to the reader some of the problem areas where he or she may want to be alert; e.g.: package insert information, package designs, labeling, unusual or improper drug product appearance.

# Syringe Graduates

After an injectable antispasmodic became available in prefilled 2 ml syringes, several hospital pharmacists reported that the syringe lacked graduated markings for a partial dose. They furthermore noted that the label stated the amount of drug present in mg per ml without making clear there were 2 ml present in the unit. The manufacturer plans to use calibrated syringes in the near future.

# **Box-Work Orange**

An Oregon pharmacist prophesied that in a tense situation, hospital personnel would mistake the units of drug per ml. declared on the label as the amount of drug present in the 0.5ml syringes. Although the prefilled 0.5ml syringes of heparin correctly listed the units per 0.5ml on the label also, it was done in orange print; the number of units per ml. were listed in bold black print. To avoid this possibility the manufacturer deleted the "units per ml" statement on the boxes of the various strengths of heparin syringes.

# (IV Additive

A community pharmacist from Florida reported that the label of chloral hydrate capsules manufactured for a distributor lacked the control symbol (V). The firm informed USP that the label was corrected after the labeling problem was brought to their attention.

# Diagnostic Error

An in-vitro diagnostic used to test for sugar in the urine had an incorrect package insert belonging to another form of the same product. The incorrect insert would have resulted in an inaccurate interpretation of test results. When an Indiana community pharmacist's observations were brought to the attention of the manufacturer through the DPPR program, the lot involved was recalled.

### Spell It Out

A unit dose package of Phenobarbital Tablets was labeled with only an abbreviated form of the drug name, "pheno". A Rhode Island pharmacist pointed out that this common two syllable prefix could denote several drugs or chemicals. The manufacturer reviewed the situation after receiving the report and redesigned the unit dose labeling to show the entire name.

### What's the Score

A suburban Washington, D.C. pharmacist telephoned a report on tablets used for myasthenia gravis. He estimated that one out of every four times, the top of the tablet would cap when trying to break the tablet in half at the score mark. The manufacturer sent a copy of the report to their production department for comment and evaluation. The production department noted a new

set of punches was being used in the tableting process, that the score was not as deep as with the old punches, and this might have caused the problem. They discontinued these punches and ordered a new set of deep score punches.

# One Coat Does Not Fit All

Two lots of an antihypertensive were recalled when a New York pharmacist reported he had found a variation in the individual tablet identification numbers. The firm determined that two strengths of the tablet had been film coated the same color and packaged together although the respective product numbers were correctly stamped into the tablets. Their normal control procedures had not caught the error.

# How Do I Count the Ways . . .

Two reports concerning split tablets with an odor led to an investigation by the FDA of a steroid-vitamin product. As a result of this investigation a seizure action was initiated by FDA charging several violations of the Federal Food, Drug, and Cosmetic Act. The charges were based on the failure to analyze for the steroid active ingredient, labeling violations, and that the product was a new drug without an approved New Drug Application.

# **USP Hot Line**



# When you call USP, please be ready to provide:

- 1. Your name
- 2. Pharmacy address, zip code, and phone number
- 3. Product name (please spell out), strength, etc.
- 4. Lot number, expiration date (if available)
- 5. Date purchased and source (if known)
- 6. Manufacturer's name and address
- 7. Labeler's name and address (if different than Mfg.)
- 8. Problem noted (please be brief, but complete)

\*In Maryland, call collect (301) 881-0256 between 9:00 AM and 4:30 PM

# Liability Protection (It comes with every tablet you dispense)

A recent article on pharmacy law stated that "it is not unlikely that pharmacists substituting therapeutically or bioequivalent drugs for those prescribed will face increasing confrontation in the courts on the issue of their liability for unanticipated or ad-

verse reactions from drugs dispensed by them"\*

It should be reassuring to know, therefore, that McNeil Laboratories stands

behind you every time that you fill a prescription for TYLENOL® with Codeine tablets or elixir-and, for that matter, for every McNeil product you dispense. The "McNeil Pharmacist Protection Policy" gives you this assurance. (If you don't already have a

> copy, you might like to send for one.)

> With the many problems facing the pharmacist today, why risk unnecessary liability problems.

\*From a special report reprinted from U.S. Pharmacist 2(4):18-23, 1977: "Pharmacy Law," by Michael R. Sonnenreich, J.D.



# Experience, Expectation and Surprise In The Quest For Health

by John C. Krantz, Jr., Ph.D.

"Tomorrow and tomorrow and tomorrow creeps in its petty pace from day to day . . ." the words of Shakespeare describe the way of life adopted by the masses of human beings destined to live upon this planet. They seek good health for it offers an absence of pain and the ability to be mobile and grasp the opportunities that afford emotional satisfaction. They live by trusting their experience of the past and sharing the observed experience of others. The experience is coupled with expectation. They know that disease is the arch enemy of the race and is continuously lying in ambush to thwart their tranquil balanced condition between experience and expectation, by some devastating disease or death.

Those workers in the health sciences share this tenuous attitude of life with the masses, but their focus on the horizon envisions the stimulating phantom of surprise. They believe there are no incurable diseases but only those diseases for which we have not yet discovered the cure. They have faith in the surprise of discovery, the increment of progress, the differential coefficient on man's curve of knowledge. They hear the voice of master investigator Paul Ehrlich echoing through the mists of an everlengthening past declaring, "I have made a drug to cure a mouse of syphillis and I shall make another to cure a million men." His dream was realized and surprise scored a victory over experience and expectation.

These surprises in the past have been sufficiently numerous to change the whole pattern of life upon the planet. At the time of the Roman empire, the life expectancy at birth was about 21 years. When William Mckinley sat in the White House it had increased to 46 years and at the Bicentennial year it has become 72 years. The reason for this spectacular increase in life expectancy becomes clear by examining the record. Between 30 and 35 billion people have lived on this planet since the beginning of the pages of written history. Fifteen percent of them are alive today. Ninety percent of the medical scientists who have lived are alive today. They are following in the footsteps of their forebears in the quest for health with ardor and determination.

Let us review just a few of these welcome surprises from which man has been afforded a longer and healthier life.

During the Spanish conquest of Peru by Francisco Pizarro in the fifteenth century, the Spaniards learned of the cinchona bark as a cure for malaria. It was taken to Europe and the French pharmacists Pelletier, Caventou isolated quinine from the bark in 1820. It was the first specific drug and was useful in the cure of one of the most devastating diseases, malaria. Quinine has been followed by several synthetic drugs and the thwarting of this human plague has been a great boon to humanity.

Edward Jenner was told by an unidentified English country girl in the latter part of the 18th century that she could not contract pox because she had cow pox. Later Dr. Edward Jenner, pursued this idea and the Jenner smallpox vaccine became available to prevent this dreadful disease.

Opium had been known to the ancients as a plant product that would reduce pain and cause sleep. It remained, however, for a young German apothecary, Frederick W. A. Serturner, to isolate morphine in 1803 from the opium powder and demonstrate its power to relieve pain. The great English physician, Thomas Sydenham, stated, "No one would be calloused enough to practice medicine without opium." Morphine and its derivatives are man's potent remedy against intractable pain.

The derivatives of opium evoke addiction and are indicated only in severe pain owing to the addictive risk.

The pains that beset the human frame are frequent and numerous, such as headache, neuromuscular pains and the unrelenting joint pains of arthritis.

In 1763 the Reverend Edward Stone reported to the Royal Society of England concerning his use of the powdered willow bark in the treatment of fevers. This started a chain of events. The bark was found to contain salicylic acid which was later made synthetically. Sodium salicylate was found useful in rheumatic disease. To treat his father, who had rheumatic disease and did not tolerate sodium salicylate well, Felix Hoffman, made acetyl-salicylic acid or aspirin. It appeared to meet the tremendous need for non-addictive pain reliever and in America alone we ingest between 20 and 30 tons of this remedy daily. It is a remarkable drug with an outstandingly high benefit/risk ratio. No other drug can parallel its use and safety record.

Sir Alexander Fleming was a Scottish physician with a strong penchant for microbiology. He observed a culture of streptococcus aurens contaminated by a mold and discovered that where mold grew the bacteria did not grow. So he speculated that there was a constituent in the mold that was inimical to the growth of bacteria. With painstaking experiments, Fleming, Chain and Florey pursued the project which led to the isolation of penicillin. Numerous other antibiotics were to follow the great surprise that came with the discovery of penicillin.

While the masses of people on this earth continue their lives balanced between experience and expectancy and frequently enclosed in the "narrow aisles of pain" the quest for health continues unabated. The past surprises point a gateway to the future and through it those engaged in the quest for health will salley forth to achieve new surprises for they are the architects of surprises.



# Gerry Hietala, Abbott research pharmacist, on flavoring:

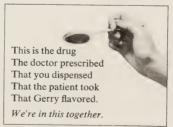
"One 'yuck' from any of these panel members and it's back to the drawing board. This is the final, most critical test for flavoring in our suspensions. No matter how much effort goes into the flavoring system of a pediatric drug, this is the bottom line. Kids simply won't take a bad-tasting medicine.

There are two basic objectives in flavoring a suspension; first, naturally, you want to mask the drug taste. Erythromycin is a prime example. It's bitter. Second, you want to maximize flavor stability. Over a period of time even insoluable drugs will hydrolyze to a limited extent. The flavoring must be able to cover the increased bitterness to maintain palatability of the suspension.

We've developed a product that minimizes the amount of free erythromycin base that will develop, and we carefully control the quality of the starting drug. These two factors assure long-range stability . . . and

good taste . . . when the product is out in the field.

Quality is built into our product through a sophisticated system of flavor assessment. We utilize statistical preference testing in addition to the flavor profile method. These help us to arrive at a top quality taste and assure that it will be maintained in production. The result is a good-tasting product with maximum stability... medicine a sick kid is going to take for ten days without a single 'yuck'."



# ABBOTT LABORATORIES

Pharmaceutical Products Division, North Chicago, Illinois 60064

# E.E.S. BRIEF SUMMARY

ERYTHROCIN® ETHYL SUCCINATE (ERYTHROMYCIN ETHYLSUCCINATE)

### Indications:

Streptococcus pyogenes (Group A beta hemolytic streptococcus)—Upper and lower respiratory tract infections, skin, and soft tissue infections of mild to moderate severity, where oral medication is preferred. Therapy should be continued for 10 days.

Alpha-hemolytic streptococci (viridans group)—Short-term prophylaxis of bacterial endocarditis prior to dental or other operative procedures in patients with a history of rheumatic fever or congenital heart disease who are hypersensitive to penicillin.

S. aureus—Acute infections of skin and soft tissue of mild to moderate severity. Resistant organisms may emerge during treatment.

S. pneumoniae (D. pneumoniae)—Upper and lower respiratory tract infections of mild to moderate degree.

M. pneumoniae - For respiratory infections due to this organism.

Hemophilus influenzae: For upper respiratory tract infections of mild to moderate severity when used concomitantly with adequate doses of sulfonamides. Not all strains of this organism are susceptible at the erythromycin concentrations ordinarily achieved (see appropriate sulfonamide labeling for prescribing information).

Treponema pallidum—As an alternate treatment in patients allergic to penicillin. C. diphtheriae and C. minutissimum—As an adjunct to antitoxin. In the treatment

of erythrasma.

Entamoeba histolytica—In the treatment of intestinal ameliasis

L. monocytogenes-Infections due to this

Establish susceptibility of pathogens to erythromycin, particularly when *S. aureus* is isolated.

## **Contraindications:**

Known hypersensitivity to erythromycin.

### Warnings

Safety for use in pregnancy has not been established.

### **Precautions:**

Exercise caution in administering to patients with impaired hepatic function. During prolonged or repeated therapy, there is a possibility of overgrowth of non-susceptible bacteria or fungi. Surgical procedures should be performed when indicated.

### Adverse Reactions:

Dose-related abdominal cramping and discomfort. Nausea, vomiting, and diarrhea infrequently occur. Mild allergic reactions such as urticaria and other skin rashes may occur. Serious allergic reactions, including anaphylaxis, have been reported.

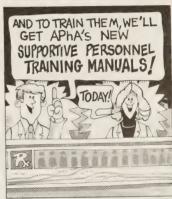












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The Trainee's Manual is the workbook used by the trainee during the training process. It gives step-by-step instructions and includes written text material as well as tests and background information.

Pharmacist's Manual: 38 pages, 22 X 28 cm, soft cover, 1978, \$10.00 (\$7,00 APhA Member Rate)

Trainee's Manual: 55 pages, 22 X 28 cm, soft cover, 1978, \$10.00 (\$7.00 APhA Member Rate)
Set of Both Manuals: \$17.00 (\$12.00 APhA Member Rate)

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The American Pharmaceutical Association—the national professional society of pharmacists

11

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# Safety Cap Use Shows

# Dramatic Drop in Children's Poisonings

The use of safety caps and closures has apparently made a dramatic impact on accidental poisonings among children, according to the latest government data.

Child-resistant closures on drugs and other hazardous products increased by 200 per cent over a three year period, according to preliminary 1977 figures released by the U.S. Census Department.

Coincidental with this increase in safety cap use, the U.S. Consumer Product Safety Commission (CPSC) reported a decrease of 47 per cent in the number of accidental poisoning deaths among children age five and under. The decrease in children's deaths is marked from 1972 when the CPSC required child-resistant caps on containers of children's aspirin.

Total safety caps shipped in 1977 equalled 1.8 billion units, an increase of 1.3 billion since 1974 when the CPSC made safety caps mandatory on all oral prescription drugs. In 1972, the number of safety closures in use could be counted in the thousands.

While the great majority of safety closures are found on prescription vials and aspirins, numerous other products are now protectively packaged — products like furniture polish, drain cleaner and turpentine have been added to the list — contributing to the dramatic increase in safety cap usage.

"The decrease in the number of deaths among children coincidental with the application of safety caps is in itself a testament to their value," reports John B. Carroll, Vice President, Closures, Glass Packaging Institute, the industry association which has been following the success of these closures in reducing accidental deaths. During National Poison Prevention Week, celebrated this past March, it was reported that:

- Accidental aspirin poisonings have declined 63 per cent.
- Accidental ingestions of methyl alcohol products (such as windshield cleaner) dropped by 83.3 per cent.
- Ingestion of controlled drugs such as amphetamines have declined 34.9 per cent.

In line with the rapid growth in safety closures used in many types of hazardous products, the Environmental Protection Agency is now working on a revised promulgation of regulations to cover the wide variety of pesticide products used in the home. A preliminary regulation was published a year ago for consideration and it is expected that a final form will be forthcoming at the end of the summer.

"However," Mr. Carroll added, "although we are making progress in poisoning prevention, a significant number of ingestions remain as a cause for concern. What is needed is a nationwide overview of what potentially dangerous poisons continue to be accessible to children in our society."

Aware that some adults find that the caps take an extra effort to remove, the closure industry and the CPSC have been engaged in educational campaigns to teach adults how to use the caps effectively. Three simple guidelines for adult consumers are:

- 1. Carefully note the directions printed on each cap; not all caps are alike.
- 2. Follow directions slowly to remove the cap.
- Be certain to replace each safety cap properly to re-establish its child-resistant properties.

Mr. Carroll noted that an essential question adult consumers should ask in relation to child-resistant closures is "Isn't it worth a little extra effort to save the life of a child?"





The Upper Bay Pharmaceutical Association met October 18 to hear a presentation by Mr. Jack Grasmick from Blue Cross and Blue Shield of Maryland.



Members of the Association met at the Flying Clipper Restaurant in Aberdeen. They also voted to make a public relations program available to local association members.

# **Local Association News**

photos courtesy of Paramount Photo Service



The Anne Arundel County Pharmaceutical Association met October 19 at the Empress Towers in Glen Burnie. Members heard a continuing education presentation on Pharmacist Liability.



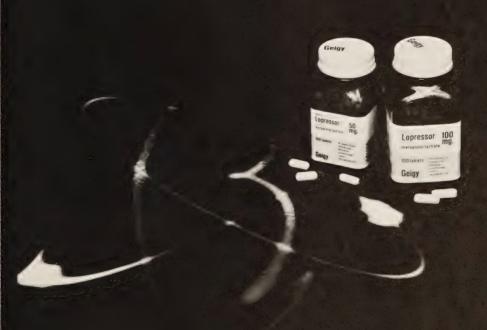
Howard Wertheim and Vince Regimenti, President of the Local Association, discuss a point before the start of the meeting.

Geigy announces a new age n beta blockade

New

# Lopressor™ metoprolol tartrate

A significant advance in the treatment of hypertension



Please turn page for brief summary of prescribing information.

# New **Lopressor**™

metoprolol tartrate

# The relatively selective beta blocker with b.i.d. dosage for hypertension

Lopressor™ brand of metoproiol tartrate

An antihypertensive beta-blocking agent

Indications Lopressor, brand of metoprolol tartrate, is indicated in the management of hypertension. It may be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics.

Contraindications Lopressor, brand of metoprolol tartrate, is contraindicated in sinus bradycardia, heart block greater than first degree, cardiogenic shock, and overt cardiac failure (see Warnings).

Warnings Cardiac Failure: Sympathetic stimulation is a vital component supporting circulatory function in congestive heart failure, and beta blockade carries the potential hazard of further depressing myocardial contractility and precipitating more severe failure. In hypertensive patients who have congestive heart failure controlled by digitalis and diuretics, Lopressor, brand of metoprolol tartrate, should be administered cautiously. Both digitalis and metoprolol slow AV conduction.

In Patients Without a History of Cardiac Failure continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, patients should be fully digitalized and/or be given a diuretic, and the response observed closely. If cardiac failure continues, despite adequate digitalization and diuretic, Lopressor, brand of metoprolol tartrate, therapy should be withdrawn.

Ischemic Heart Disease: Following abrupt cessation of therapy with certain beta-blocking agents, exacerbations of angina pectoris and, in some cases, myocardial infarction have been reported. Even in the absence of overt angina pectoris, when discontinuing therapy, Lopressor, brand of metoprolol tartrate, should not be withdrawn abruptly, and patients should be cautioned against interruption of therapy without the physician's

Bronchospastic Diseases: PATIENTS WITH BRON-CHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Because of its relative beta, selectivity, however, Lopressor, brand of metoprolol tartrate, may be used with caution in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment. Since beta, selectivity is not absolute, a beta, -stimulating agent should be administered concomitantly and the lowest possible dose of metoprolol should be used. It may be prudent initially to administer metoprolol in three doses daily, instead of two, to avoid the higher plasma levels associated with the longer dosing interval. (See Dosage and Administration.)

Major Surgery: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Metoprolol, like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in restarting and maintaining the heart beat has also been reported with beta blockers.

Diabetes Mellitus: Beta-adrenergic blockade may mask symptoms of hypoglycemia (e.g., tachycardia) and may potentiate insulin-induced hypoglycemia. Lopressor, brand of metoprolol tartrate, should therefore be used with caution in diabetic patients, especially those with labile diabetes. Thyrotoxicosis: Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyper-thyroidism. Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta blockade which might precipitate a thyroid storm.

Precautions Impaired Hepatic or Renal Function:
The drug should be used with caution in patients with impaired hepatic or renal function.

Drug Interactions: Catecholamine-depleting drugs (e.g., reserpine) may have an additive effect when given with beta-blocking agents. Patients treated with Lopressor, brand of metoproloi tartrate, plus a catecholamine depletor should therefore be closely observed for evidence of hypotension and/or marked bradycardia which may produce vertigo, syncope, or postural hypotension.

Long-Term Animal Studies: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In a one-year study in dogs. there was no evidence of drug-induced toxicity at or below oral doses of 105 mg/kg per day. Two-year studies in rats at three oral dosage levels of up to 800 mg/kg per day did not indicate an increase in the development of spontaneously occurring benign or malignant neoplasms of any type. The only histologic changes which appeared to be drug-related were an increased incidence of generally mild focal accumulation of foamy macrophages in pulmonary alveoli and a slight increase in biliary hyperplasia. Neither finding represents symptoms of a known disease entity in man. In a 21-month study in mice at three oral dose levels of up to 750. mg/kg per day, benign lung tumors (small adenomas) occurred more frequently in female mice receiving the highest dose than in untreated control animals. There was no increase in malignant lung tumors or total (benign plus malignant) lung tumors. The overall incidence of tumors or malignant tumors was also unaffected by metoprolol administration

Usage in Pregnancy: Reproduction studies in animals did not reveal any evidence of impaired fertility or of teratogenic potential. There was evidence in the rat of increased postimplantation loss and decreased neonatal survival (threshold between 50 and 500 mg/kg). Distribution studies in mice confirm exposure of the fetus when metoprolol is administered to the pregnant animal. There are no well-controlled studies in pregnant women. Lopressor, brand of metoprolol tartrate, should be used in pregnant women only when clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Since most drugs are excreted in human milk, nursing should not be undertaken by mothers receiving metoprolol.

Usage in Children: Safety and effectiveness in children have not been established.

Adverse Reactions Most adverse effects have been mild and transient.

Central Nervous System: Tiredness and dizziness have occurred in about 10 of 100 patients. Depression was reported in about 5 of 100 patients. Headache, nightmares, and insomnia have also been reported but drug relationship is not clear.

Cardiovascular: Shortness of breath and bradycardia have occurred in approximately 3 of 100 patients. Cold extremitles, Raynaud's disease, palpitations and congestive heart failure have been reported. See Contraindications, Warnings, and Precautions.

Respiratory: Wheezing (bronchospasm) has been reported in less than 1 of 100 patients. See Warnings.

Gastrointestinal: Diarrhea has occurred in about 5 of 100 patients. Nausea, gastric pain, constipation, flatulence, and heartburn have been reported in 1 of 100 or less

Allergic: Pruritus has occurred in less than 1 of 100 patients

Miscellaneous: Peyronie's disease has been reported in less than 1 of 100,000 patients.

The oculomucocutaneous syndrome associated with the beta blocker practolol has not been reported with Lopressor, brand of metoprolol tartrate, during investigational use and foreign marketing experience.

Potential Adverse Effects: In addition, a variety of adverse effects not listed above have been reported with other beta-adrenergic blocking agents, and should be considered potential adverse effects of metogroloi.

Central Nervous System: Reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Cardiovascular: Intensification of AV block (see Contraindications).

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Allergic: Erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Miscellaneous: Reversible alonecia

Clinical Laboratory Test Findings: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

Dosage and Administration Dosage of Lopressor, brand of metoprolol tartrate, should be individualized. The usual initial dose is 50 mg twice daily whether used alone or added to a diuretic. The dosage may be increased at weekly (or longer) intervals until optimum blood pressure reduction is achieved. In general, the maximum effect of any given dosage level will be apparent after one week of therapy. Usual maintenance dosage is approximately 100 mg twice a day, with a range of 100 to 450 mg per day. Dosages above 450 mg per day have not been studied. While twice-daily dosing is effective and can maintain a reduction in blood pressure throughout the day, some patients, especially when lower dosages are used, will experience a modest rise in blood pressure toward the end of the 12-hour dosing interval. This can be evaluated by measuring blood pressure near the end of the dosing interval to determine whether satisfactory control is being maintained throughout the day. If control is not adequate, a larger dose, or three times daily therapy, may achieve better control. Beta, selectivity diminishes as dosage of Lopressor, brand of metoprolol tartrate, is increased.

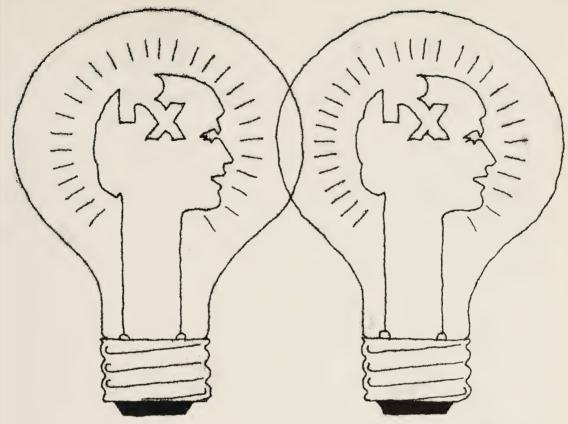
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# PRIMITE INTERPRETOR

# SHOULD IT BE MANAGED WITH DIET, DIURETICS, OR NO TREATMENT AT ALL?

The famous VA studies, <sup>1</sup> first published in 1967, provided solid evidence that antihypertensive medication is necessary to avoid the often fatal end-organ damage that characterizes hypertension in adults. But what should a physician do if he discovers primary hypertension in a 12-year-old?

The answers to this question vary, depending on one's school of thought. A recent hypertension symposium<sup>2-5</sup> collected leading authorities in the field of pediatric and adolescent hypertension to discuss this and other related problems. Here is a sample of their opinions on treatment:

Diagnosis is the key

First and foremost, Dr. J. Caulie Gunnels2 of Duke University believes the diagnosis of essential hypertension must be firmly established. "...it is of some value to again stress the importance of always considering the various causes of secondary hypertension in children presenting with sustained elevation in systemic blood pressure." However, if the diagnosis of essential hypertension is definite, Dr. Gunnels went on to say, "...it would appear unreasonable in this era to avoid the effective reduction of blood pressure....

There are various ways of accomplishing this. Before initiating drug therapy, Dr. Gunnels advocates weight reduction in the obese, a decrease in salt intake, and discontinuance of hypertension-inducing foods or drugs such as licorice or oral contraceptives. Then Dr. Gunnels would use a diuretic as the cornerstone of his therapy, moving on to a step-wise addition of hydralazine and/or propranolol.

Reduce, reduce

Dr. M.A. Holliday<sup>3</sup> of the University of California at San Francisco firmly believes that in children obesity is often a predisposing factor to hypertension. For the hypertensive child, he recommends cutting down on calories and salt intake. As the report of the Bogalusa study shows, data are accumulating that show hypertension is related to height and weight measurements rather than age, so that Dr. Holliday's point of view seems to concur with current research.

Dr. Jennifer Loggie<sup>4</sup> of the University of Cincinnati has worked with the problem of childhood hypertension for many years now. Her experience has led her to conclude that essential hypertension in the young is not rare. This is especially true in black teenagers and adoles-

cents where there is a strong family history of the disease. She recommends the reduction to or maintenance of average weight, but also recognizes that in young people this can be difficult. The maintenance of a low-calorie, low-salt diet in a society where "fast" food abounds is not always compatible with the lifestyle of adolescents, she contends. Some of her patients, she reports, can be brought to normotensive levels through the use of a diuretic.

Diagnose now, pay less later

At Columbia University, Dr. Margaret Kilcoyne<sup>5</sup> is so convinced that childhood hypertension is a common phenomenon that her studies do not focus on the incidence of the disease as much as its manifestations—particularly hemodynamic changes. Dr. Kilcoyne has treated her young hypertensive patients with both diuretics and beta-adrenergic blockers, but recognizes that more work needs to be done before any "treatment formula" can be developed.

From all of this, it is difficult to form a definitive conclusion. A variety of well-known authors each has his own opinion – though weight reduction, salt restriction, and diuretic therapy seem to be mentioned most often. Most importantly, however, the experts are willing to agree that hypertension in children is not a rare phenomenon. Watching for this disease early may do much to change the discouraging statistics of its incidence of damage in adults.

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# WEGIING THE ODDS AGAINST

# HOW OBESITY INCREASES CARDIOVASCULAR RISK

Although obesity in itself does not indicate hypertension. These significant correlations between the two suggest close association, if not direct causality:

a) a higher prevalence of hypertension among the obese than among

the nonobese<sup>2</sup>

 b) a greater risk of developing coronary artery disease among obese hypertensives than nonobese hypertensives<sup>2</sup>

 c) a higher mortality rate for those who are both obese and hypertensive than for those with either problem alone<sup>2</sup>

d) an increased incidence of hypertension in proportion to the degree

of overweight.3

Nor is the connection limited to extreme obesity. A positive correlation between blood pressure and relative weight has been observed throughout the range of blood pressures and weights recorded in a

population.3

Several postulates have been proposed to explain the "obesity connection" to hypertension. Evidence that salt intake is related to hypertension has prompted one investigator to point out that "...an increased food intake obviously involves an increased sodium intake." It may be just as simple as that, but then there is the fact that obesity "...can increase oxygen consumption at rest, increase work when moving, and thus increase cardiac output and peripheral resistance."

Stress, too, has been noted as a contributory factor in the pathogenesis of hypertension.<sup>5</sup> The obese individual is subject to psychological stress beyond the norm, engendered by the prejudices of "... a culture that is hostile and derogatory towards even mild degrees of overweight..."6 and "... the tension and conflicts that are precipitated by efforts at reducing." 6 Obesity can sometimes serve to mask an inability to adequately cope with stress. The profile of an obese person who compulsively overeats in response to stress is a familiar one.

Of course, obesity is implicated not only in hypertension, but in coronary artery disease and other cardiovascular conditions as well. An increase in food intake in our society generally means an increase in total fat intake, specifically saturated fats and cholesterol. Research demonstrates the association between hyperphagia and hypercholesterolemia, and between inactivity and heightened cholesterol.<sup>4</sup>

The overall effect of obesity on blood pressure is to increase cardiac work load, thus increasing the probability of death from coronary artery

disease.7

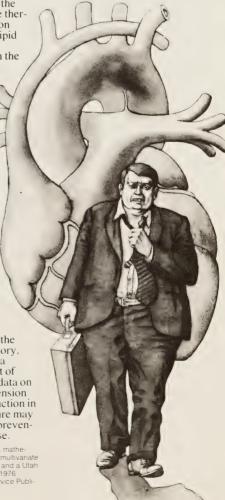
Reports of accelerated atherosclerosis in obese hypertensives show that without intervening treatment, pronounced premature aging of the arteries located at the base of the brain can occur.<sup>8</sup> Appropriate therapy includes a weight reduction program designed to correct lipid abnormalities.<sup>9</sup>

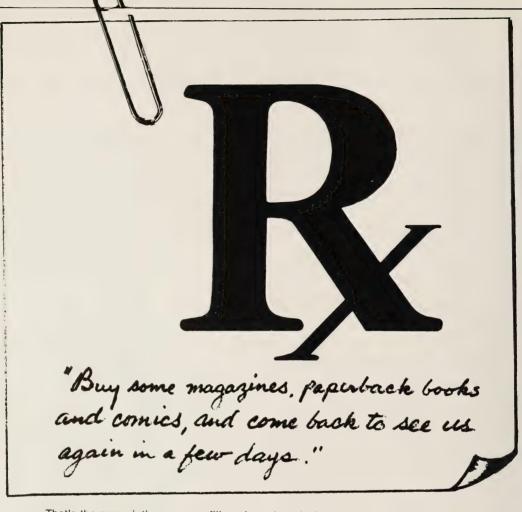
Respiratory difficulties in the obese—from a general difficulty in breathing and a diminished tolerance for exercise, to the extreme Pickwickian syndrome (which may progress to a reactive polycythemia and attendant thromboses)—present another related constellation of problems which can take their toll on the cardiovascular system.<sup>2</sup>

The validity, and sometimes critical importance, of including a weightreduction program in almost any therapeutic regimen designed for the obese patient is clear. In the presence of hypertension, a consideration of diet, exercise, and living habits should be included as an integral part of the evaluation procedure - from the initial taking of a medical history, through the establishment of a management plan. In the light of existing and ever-increasing data on correlations between hypertension and obesity, a combined reduction in both weight and blood pressure may well be most effective in the prevention of coronary artery disease.

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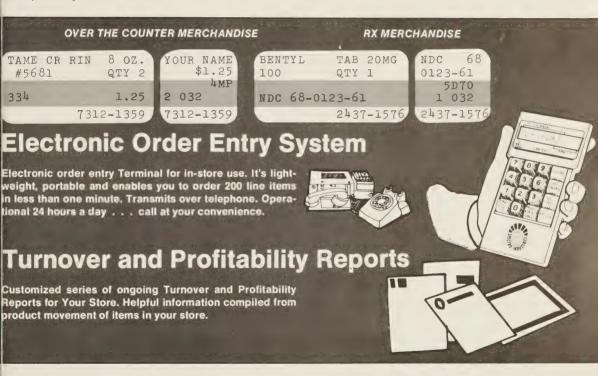
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# Report a suspect Earn a reward Dial: 685-BUST

MEMBER
BUSINESS UNITED TO STOP TROUBLE

The Baltimore Metropolitan Pharmaceutical Association supports BUST for area pharmacies. Contact the office for information on how to join and support this group of Businessmen United to Stop Trouble.

A Public Service of This Magazine A The Advertising Council



# Your Business can be one too.

Red Cross needs individual volunteers, and donors of blood and money, by the millions.

But we need even more help. We need the solid support of American Business. And we never needed it more.

If your business is already helping, by organizing blood drives, and by supporting payroll deductions—either directly for the Red Cross, or through the local combined fund drive—the whole community owes you thanks. And we thank you, too.

Last year, with help from our friends, we offered major aid at over 30,000 disasters from typhoons, to local (but just as devastating) house fires.

We were able to help the elderly with practical programs, we helped veterans by the hundreds of thousands, we taught people by the millions to swim or swim better. And that's just the tip of the iceberg.

Think of America without The American Red Cross.

And you'll know why we need your business as a Red Cross Volunteer. In your community. And all across America. Contact your local Red Cross Chapter to see how your company can become a volunteer.

Red Cross is counting on you.

NOVEMBER. 1978 25

# Trace your debt-defying customers

Members of the Maryland Pharmaceutical Association now have a uniform collection system approved for their use. It's offered by I. C. System, Inc., and employs the latest techniques available, consistent with all requirements and provisions of the increasingly strict laws governing collection practices.

I. C. System, Inc., has been in the collection business since 1938. It now serves the members of close to 1,000 state business and professional associations all across the country. During 1977 the company collected an all-time record of \$22.6 million in past-due accounts.

All collection practices, procedures and materials used by I. C. System have been scrutinized by the Federal Trade Commission. So without reservation, all members can be assured that the company is fully aware of what can and cannot be done on behalf of its clients. And in view of I. C. System's preeminence in size and prestige within the industry, members can be assured that they are in no danger of legal action resulting from collection activities carried out on their behalf. That's particularly important in this age of consumerism. A few short years ago, the most important consideration in selecting a collection service was in determining its ability and willingness to turn over to the creditor all the money he had coming to him. Today, such selection equally emphasizes the importance of entrusting the businessman's good name and reputation to the collection service . . . a heavy responsibility.

Keeping pace with the increases in collections over the years has been development of improved processing and customer service departments in their home office. The company has a modern, tailor-made data processing system from Control Data and IBM. For the benefit of those familiar with computer systems, theirs is an on-line Control Data Omega 480 with an IBM 3211 printer serving IBM 3270 cathode ray tube terminals. This system is backed up by automatic typewriters, microfilm equipment and a complete in-house printing and mailing capability. For those not familiar with such equipment, it simply means that company growth hinders neither their effectiveness nor their ability to respond immediately to customer needs and inquiries.

We believe that the results of even the most thorough skip-tracing attempts by an outsi agency do not justify the costs involved. You are the first to know if a debtor has skipp. That's why you are your own best skip-tracing service.

As a creditor, you have special information available only to you for tracing the non-criminal effectively at considerably less cost. But you have to act fast. It is best, in fact, to begin a trace whenever the Post Of returns a statement it can't deliver. Because once a debtor has covered his tracks, it is oft too late. Here's what to do:

Check all references on credit application forms and then try one or more of the follow methods:

 (a) Address an envelope to the debtor at the last known address. Indicate in the up left-hand corner of the envelope (beneath your return address) as follows: "ADDRESS CORRECTION REQUESTED" When the letter is forwarded, you will be notified by the Post Office and charged 2

The company maintains a staff of Customer Relations personnel whose job it is to see that all customer inquiries are handled on a "right now" basis. And for those situations in which the mail cannot carry information fast enough, the creditor can telephone the company via their toll free WATS line system.

Borrowing from the experience of users in other



) Send a mailing list for updates to the stmaster at the city of the last known ldress along with a \$1.00 money order or ertified check (10¢ extra for each name ver 10). If he has the forwarding address, ou'll get it. If not, he'll let you know.

EMEMBER: This method may take several eeks, so the sooner you get the ball lling, the sooner you'll get the information.

) Send a certified letter to debtor's last nown address, requesting a receipt and ldress where delivered.

one of the preceding methods will work if debtor has notified the Post Office of orwarding address.

heck with the school where the debtor's dren last attended. Schools are required to sfer records.

heck both city and telephone directories.

iquire of church, union, lodge, friends, hbors and relatives of the debtor.

ontact gas and electric company, water pany, moving and storage company.

**6.** Contact the Motor Vehicle Registration Department in the state where debtor moved.

**7.** Contact loan institutions. They are usually most cooperative.

8. Bank. The debtor's bank will not give you information, but you may ask your own banker to obtain it for you.

9. Last employer.

**10.** Service men — If you can identify the branch of service, direct your inquiry to the Locater Service listed below and enclose \$2.00 as a fee for the service.

NAVY: Locater Service, Bureau of Navy Personnel, Arlington Annex, Arlington, Virginia 20370.

ARMY: Locater Service, Military Personnel Center, Hoffman Bldg., 200 Stovall Street, Alexandria, Virginia 22332.

AIR FORCE: Locater Service, Air Force, Pentagon, Washington, D.C. 20330.

states, members of the Maryland Pharmaceutical Association who install the system should submit nine or more accounts immediately. Even if it's necessary to go back a year or more to come up with that many bad checks or written off accounts, it's well worth the effort. You can't expect as high a percentage of collections on the very old accounts, but the initial heavy use will get your book-

keeper accustomed to working with the service and thus less likely to forget to submit future accounts as they become 60 or 90 days past due. A company representative will be happy to spend some time with your bookkeeper to start things off on the right foot.

To learn more about how the service can help you, simply contact the Association office.



## "I choose a product because of..."

Product quality . . . 99 percent of all Lilly and Dista products are manufactured by Eli Lilly and Company or its wholly owned subsidiaries, and the dating on Lilly and Dista products is backed by continuing stability studies.

**Dosage unit identification . . .** Each individual dose of Lilly and Dista solid oral products carries the company name and a product name or code.

**Research** . . . Lilly continues to seek new and better ways to prevent and treat disease and thus improve the quality of life for mankind.

**Distribution** . . . Lilly and Dista products are readily available from about 400 service wholesalers coast to coast and in Hawaii and Alaska.

**Return goods policy...** Lilly and Dista products may be returned for exchange at full value up to one year after the expiration date.

**Sales representatives** . . . 75 percent of all Lilly and Dista representatives are pharmacists; most others have degrees in the life sciences.

**Pricing...** There is no differential in the prices of Lilly and Dista products sold to wholesalers for resale to independent and chain pharmacies.

**Management assistance** . . . The Lilly Analysis Service, *Lilly Digest*, and *NACDS-Lilly Digest* provide ready information and assistance.

Educational programs . . . Lilly offers five courses for individual study and five audio-visual programs—all approved by most states that require continuing education.

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No wonder nearly five generations of pharmacists have depended on



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### **Association Honors WCAO-WXYV-FM**



Hon. Hubert S. Humphrey Pharmacist Vice President, U.S.A. Senator, U.S.A.



Graduate 1933 Denver College of Pharmacy



Hubert Humphrey covers like this one are part of a memorial window display which has been shown at Cavacos Pharmacy, 36th Street at Roland Avenue in Hampden. The extensive Cavacos Pharmacy collection has also been on display at the Humphrey Museum on Capitol Street in Washington, D.C. In Baltimore, the Science Museum has featured an old soda fountain exhibition and items from the Cavacos collection.

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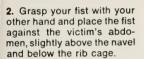
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### FOR CHOKING ON FOOD FOLLOW THE HEIMLICH MANEUVER\*

\*TM pending

1. Stand behind the victim and wrap your arms around his waist.





Repeat several times if necessary.

3. Press your fist into the victim's abdomen with a guick upward thrust.

When the victim is sitting, the rescuer kneels on one knee behind the victim's chair and performs the maneuver in the same manner. OR—if the victim is lying on his back—

- 1. Facing victim, kneel astride his hips.
- 2. With one of your hands on top of the other, place the heel of your bottom hand on the abdomen slightly above the navel and below the rib cage.
- 3. Press into the victim's abdomen with a quick upward thrust.



Repeat several times if necessary.

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NOVEMBER, 1978 31

# We're listening, Yakima, Washington

"A good program for returning merchandise is one of the most important services that a manufacturer can offer the pharmacist," says Pharmacist Bruce Wherry of Yakima, Washington,

"Because I'm a businessman as well as a professional, this cooperation in returning products is a financial necessity to me. More than that, it represents a gesture of good faith from the manufacturer to me, and it's a critical building block in our relationship.'

# We hear you, **Bruce Wherry**

We agree, Mr. Wherry. Because SK&F distributes

through wholesalers, we pay SK&F wholesalers to provide this important service. SK&F wholesalers are responsible for taking back unopened bottles of active or discontinued products that don't sell. Because they have regular and close contacts with their pharmacy customers, the processing of claims through wholesalers is more convenient, more expeditious If there's a special problem that the wholesaler can't handle, contact your SK&F Representative, Chances are good that the difficulty can be resolved quickly—and to your satisfaction. The company that's interested in you. Smith Kline & French Laboratories POTTERS D'R'U'G

### THE MARYLAND PHARMACIST

Official Journal of The Maryland Pharmaceutical Association

DECEMBER, 1978 VOL. 54 NO. 12



Results of Myers and Stauffer Dispensing Cost Survey

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Lilly Digest Results and Hospital Pharmacy Survey

Shoplifting:

A battle we can't afford to lose

### THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET BALTIMORE MARYLAND 21201 TELEPHONE 301/727-0746

DECEMBER 1978

VOI. 54

NO. 12

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DAVID A BANTA Editor SHARON SPIES, Assistant Editor ABRIAN BLOOM, Photographer

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### HMO'S:

### A Hazard to your Health

Recently the Association has become aware that one of the six existing Health Maintenance Organizations (HMO's) in Maryland has entered into an exclusive agreement with the Giant chain to provide pharmaceutical services for its subscribers. This HMO is the Clinical Associates Medical Plan located on York Road in Lutherville. Sounds like a violation of the ''freedom of choice'' principle — right? While the Association is still investigating this situation, this more than demonstrates the potential hazard to pharmacy which the HMO's represent. The Staff, Third Party Committee and the Board of Trustees are concerned about the unfair competition of these exclusive agreements with HMO's. Now is the time to speak out against these threats to our profession.

Dave Banta and I had an opportunity to meet with the NARD Executive Committee in Hot Springs, Virginia recently to discuss this issue and many others confronting your pharmacy practice.

Be sure to watch for a letter from PharmPAC which should explain the current status of the proposed class-action suit against the State. Be sure to attend the next PharmPAC general meeting. I am certain it will be the most important meeting in recent years.

If you have any comments, suggestions or input on any of the above, I would appreciate hearing from you.

Harry Joy John

DECEMBER. 1978

### Results of Myers and Stauffer

# \*\*\*\*\*\*\***\$**

# Dispensing Cost Survey

On November 23, 1977, the State of Maryland awarded the firm of Myers and Stauffer, CPAs, Topeka, Kansas, a contract to conduct a survey of the cost of dispensing pharmaceutical prescriptions in the State of Maryland. So that the most up-todate data could be utilized in carrying out the terms of the contract, it was agreed between the involved parties that survey data collection would be delayed until after calendar year 1977 data would be available from those pharmacies chosen to participate.

From a statewide total population of 891 pharmacies, 196 were eliminated, leaving a net population of 695 pharmacies. The elimination of the 196 pharmacies included those pharmacies with 200 or less Medicaid prescriptions which represented 22 percent of the pharmacies but less than one percent of the total Medicaid prescriptions. Of these 695 pharmacies, 435 were randomly selected to receive cost reports. Twelve of the selected pharmacies were found to be out of business, therefore, 423 was the final number of pharmacies available to file.

Editor's Note: This article was prepared for THE MARYLAND PHARMACIST by the staff of Myers and Stauffer, Certified Public Accountants, 909 Topeka Avenue, Topeka, Kansas 66612. Their firm has recently completed a pharmacy cost survey in Maryland. Mr. Myers and Mr. Stauffer are certified public accountants who have taught accounting at the university level for a number of years before going into public practice. Mr. Miller is a pharmacist and an attorney with many years of experience in community pharmacy. He is the President of the American Pharmaceutical Association and is recognized as an authority on variable tee system. All three authors have several years of experience with cost related pharmacy tee systems.

On February 7, 1978, survey instruments and instructions were sent to the 435 pharmacies selected to file. A telephone number encouraging the pharmacist or his accountant to call collect was also made available for questions concerning the completion of the cost reports. A follow-up letter was sent on April 13, 1978, encouraging each selected pharmacy that had not yet filed to complete the survey.

By April 28, 1978, approximately 133 cost reports had been received. By June 14, 1978, a total of 144 independent or small chain pharmacy entities, and four large chain entities (representing ninety chain pharmacy units) had filed cost reports. A few more cost reports were received after that date. The final printouts indicated that 227 usable cost reports were received. Of these 227 cost reports, 137 were individual stores and 90 were large chain stores.

The cooperation extended by the participating pharmacies, the Maryland Pharmaceutical Association, and the Maryland Association of Chain Drug Stores was gratifying. Especially Dave Banta and members of the Maryland Pharmaceutical Association devoted considerable time in contacting individual pharmacies to help elicit their cooperation. Without this cooperation, the survey would most certainly have been a failure.

The January, 1978 issue of THE MARYLAND PHARMACIST contained a summary of the procedures which were used in conducting the survey and determining prescription costs. This report will therefore be restricted to reporting on the results of the survey.

Included with the cost survey was a survey of the participating pharmacy's usual and customary costs and selling prices. The number of pharmacies who filed the usual and customary survey was 127 out of the 137 independent and small chain pharmacies who also filed the cost survey. None of the four large chains representing 90 pharmacies filed the usual and customary surveys. Because of the resultant low response rate, it was recommended that a determination of reasonable profit not be made based upon the usual and customary survey.

The cost survey was initiated by the state agency to facilitate the study of various alternatives for a dispensing fee calculation. Apparently the State of Maryland intends to continue its present policy of utilizing one statewide fee in reimbursing providers of pharmaceutical services. However, the survey results allow the consideration of various options other than the selection of a uniform statewide fee. For example, a number of alternatives by percentiles, methods of calculating means. et cetera, could be used. As shown in Table 1, three types of means were calculated. First, the mean weighted by Medicaid volume is the average cost of filling a prescription using Medicaid prescription volume as weights. (The weighted mean calculation implies that low Medicaid volume pharmacies have a smaller impact than high volume pharmacies.) The mean weighted by total prescription volume is the average cost of all prescriptions dispensed by pharmacies included in the sample. Finally, the unweighted mean is the average

cost using equal weights for each pharmacy. Of these three, the best estimate for the average total cost of filling a prescription in the State of Maryland is the mean weighted by total prescriptions. The mean weighted by total prescriptions is \$2.84

Table 1 can be considered an overall summary of survey results. Since this table deals only with averages, it does contain data submitted by large chain organizations.

Table 2 illustrates average cost by various categories such as location. ownership, et cetera. The total cost column shows that costs vary according to these various categories. However, in most cases, this variation is assumed to be random. Only the category of prescription volume shows cost variation that is statistically significent. There appears to be a definite relationship between prescription volume and cost per prescription. Table 2 reflects only survey data submitted by individual and small chain operations.

(continued on page 6)

#### TABLE 1 MARYLAND PHARMACIES Inflated to December 1978

Summary of Means of Cost and Sales Per Prescription For Large Chain and Non-Large Chain Pharmacies

	Labor	Overhead	Total	Sales
Large Chains				
Mean Weighted by				
Medicaid Rx's	\$2.34	\$ .73	\$3.06	\$5.51
Mean Weighted by				
Total Rx's	2.36	.70	3.06	5.50
Unweighted Mean	2.37	.69	3.07	5.5
Number of Pharmacies				
90				
Non-Large Chains				
Mean Weighted by				
Medicaid Rx's	1.91	.88	2.78	6.30
Mean Weighted by				
Total Rx's	1.83	.82	2.65	6.18
Unweighted Mean	2.01	.84	2.84	6.2
Number of Pharmacies				
137				
Total Reporting Pharmacies				
Mean Weighted by				
Medicaid Rx's	2.00	.84	2.84	6.14
Mean Weighted by				
Total Rx's	2.08	.77	2.84	5.8
Unweighted Mean	2.15	.78	2.93	5.9
Number of Pharmacies	2.70	., 0		010
227				

Medicald volume is based upon the Maryland Medical Assistance Programs Pharmacy Vendor Summary, dated 10-17-77, for Medicaid prescriptions paid with a cost fee. This excludes Medicaid OTC prescriptions and prescriptions bearing reduced charges due to usual and customary limitations.

TABLE 2 MARYLAND PHARMACIES Inflated to December 1978

Summary of Means Weighted by Total Prescriptions Excluding Large Chains

							Test of Tota	
	No. of Pharmacies	Labor	Overhead	Total Cost	Selling Price**	Calculated Value	Critical Value	Significant Differences
All Pharmacies	137	\$ 1.83	\$ .82	\$ 2.65	\$ 6.18	5.52	7.81	no
Ownership								
Individual	28	1.68	.67	2.35	6.06			
Partnership	8	2.12	.69	2.81	6.59			
Corporation	100	1.85	.86	2.71	6.17			
Other	1	1.12	.74	1.86	6.39			
_ocation						5.27	7.81	no
Downtown or Neighborhood	87	1.75	.75	2.50	6.17			
Shopping Center	28	2.14	.80	2.94	6.13			
Medical Office Bldg.	14	1.78	1.11	2.89	6.26			
Institutional Pharmacy	8	1.62	1.26	2.88	6.34			
Affiliation						.19	3.84	no
Independent	132	1.84	.81	2.65	6.21			
Chain (5-14 units)	5	1.71	1.08	2.79	5.44			
Prescription Volume						24.86	9.49	yes
10,000 and under	8	2.72	.95	3.67	6.80			
10,001 to 20,000	42	2.36	.96	3.32	6.25			
20,001 to 30,000	42	1.83	.77	2.60	6.24			
30,001 to 40,000	25	1.67	.77	2.44	5.99			
40,001 and above	20	1.60	.82	2.41	6.18			
Building						2.67	3.84	no
Owned	23	1.80	.70	2.50	5.88			
Rented	114	1.84	.84	2.68	6.23			
Patient Profiles						.20	3.84	no
Yes	80	1.77	.87	2.63	6.21			
No	57	1.94	.75	2.69	6.13			
Jnit Dose						.0005	3.84	no
Yes	8	1.70	1.11	2.81	6.79			
No	129	1.85	.79	2.64	6.10			
Metropolitan/Not Metro						3.10	5.99	no
Baltimore	49	1.91	.79	2.70	6.26			
Washington, D.C.	6	2.07	.89	2.96	5.86			
Not Metropolitan	82	1.78	.83	2.61	6.15			

<sup>\*</sup>A Chi Square analysis to test if samples came from populations with identical distributions. Level of significance is 5%.

Prepared without audit by Myers and Stauffer, Certified Public Accountants, Topeka, Kansas.

Source: Schedule D, July 25, 1978, for the 227 responding pharmacies with fiscal years generally ending on or before December 31, 1977.

NOTE: Some amounts may not add due to rounding. Prepared without audit by Myers and Stauffer, Certified Public Accountants, Topeka, Kansas. Source: Various sorts and sequences of Schedule D. Dated July 25, 1978.

<sup>\*\*</sup>Selling price has not been adjusted for inflation.

TABLE 3
MARYLAND PHARMACIES
Inflated to December 1978

Total Operating Cost Per Prescription by Prescription Volume Excluding Large Chains

Percentile	10,000 and Under	10,001 to 20,000	20,001 to 30,000	30,001 to 40,000	40,001 and above	All Pharmacies
90	\$	\$ 4.63	\$ 3.57	\$ 3.09	\$ 3.25	\$ 3.92
80		4.06	3.37	2.74	2.99	3.59
70		3.78	2.95	2.69	2.79	3.35
60		3.52	2.60	2.46	2.43	2.99
50	3.62	3.39	2.50	2.37	2.21	2.70
40		3.04	2.31	2.30	2.11	2.46
30		2.78	2.03	2.07	2.01	2.28
20		2.65	1.95	1.84	1.61	2.02
10		2.07	1.63	1.68	1.61	1.76
Mean Weighted by Medicaid Rx's	\$ 3.68	\$ 3.45	\$ 2.43	\$ 2.68	\$ 2.55	\$ 2.78
Mean Weighted by Total Rx's	3.67	3.32	2.60	2.44	2.41	2.65
Unweighted Mean	3.83	3.35	2.61	2.44	2.39	2.84
Number of Pharmacies	8	42	42	25	20	137

Prepared without audit by Myers and Stauffer, Certified Public Accountants, Topeka, Kansas.

Source: Schedule D, July 25, 1978, for the 137 responding pharmacies with fiscal years generally ending on or before December 31, 1977.

Large chains are excluded in Table 2 since they are not reported on an individual store basis. Data provided by the large chains was usable in determining average cost but was not found to be applicable to statistical tests or percentile arrays.

It should be emphasized that the cost data that pharmacies submitted was based on historical costs incurred during reporting periods generally ending on or before December 31, 1977. Reported costs were not the same as those that will be incurred during the fee payment period.

Additionally, profit, or net margin, is an important factor to be considered in setting a reimbursement rate. One purpose of the usual and customary survey was to determine an average profit per prescription. As stated earlier, it was believed that the participation rate by pharmacies in completing the usual and customary survey was inadequate for the surveys to be used for this purpose.

Table 3 illustrates percentile arrays of total cost per prescription by various volume classifications. It may be a useful exercise for a pharmacist to compare his particular pharmacy's

per prescription data to the appropriate volume classification contained in Table 3. It should be pointed out that averages can be misleading when compared with individual items contained in that data, particularly if the deviations are as wide as those indicated in Table 3. Similarly. comparisons can be made to the data contained in Table 1. This may give some indication of problem areas in which it may be profitable to concentrate some additional managerial and professional effort. For example, if total cost per prescription is about average but labor cost is high, the pharmacist may do well to consider ways of reducing labor cost per prescription. As a management tool, this procedure is relatively unsophisticated in that it does not indicate specifically what should be done. At best, these comparisons may only indicate a problem area for your attention and analysis. It is hoped that the results of this survey can be of some benefit to Maryland pharmacists as an aid in managerial decision-making as well as providing a means of fairly calculating the cost basis of a professional pharmacy fee.

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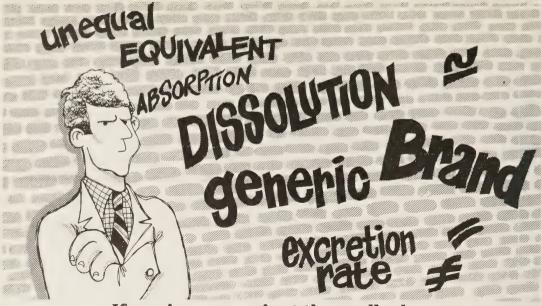
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William F. Holin, Vice President for Public Affairs of the Maryland Chamber of Commerce (right) discusses the topic of political involvement. Milton Sappe, Speaker of the MPhA House of Delegates (center) presided over the Fall Regional Meeting held October 26th. Delegate Thomas B. Kernan, Democrat-District 10, Baltimore County (left) also participated in the program.



MPhA President Stanley Yaffe (left) presents the outgoing Speaker of the House Award to Samuel Lichter (right) the 1977-78 Speaker.

Pictures courtesy of Paramount Photo Service

# Politica is Fal

(Closing remarks of William Holin)

Having heard from the real authorities on this subject, you now should be ready for a recap of some of the major lessons to be learned here today.

First, never register to vote. This may help lead to the election of someone who is sympathetic to your views.

That brings us to Number 2, a corollary, never vote in the primary or the general election. An overabundance of labor sympathizers, environmental zealots, and consumer activists in the legislature is elected by business people who don't vote.

Never contribute money to a campaign of candidate. You can always think of a good reason not to contribute and be sure your legislator knows about your lack of generosity.

Never work in an election campaign for a candidate for public office. Your effort may actually help some worthy candidate get elected.

Make no attempt to know your legislators personally. This may give you easier access to them when you need it, and it may also lead to obligations that you would not have to those you haven't even met.

Never approach your legislators unless you are seeking some special favor or threatening them. They'll be very receptive to your approach under these circumstances and are sure not to act as you desire.

When you make a complaint, in person or in writing, be sure that it's in your best scathing invective. Do this publicly so that they are embarrassed. Public abuse is appreciated by everyone.

Never praise your legislators for something they have done. They're not human like us and they are probably too busy to notice your saying you appreciate something they've accomplished.

Always demand instant action, particularly on the more impossible demands. Ignore the fact that the legislative process involves many people and many steps and demand the performance of miracles.

Be as unreasonable as possible. And, by the same token never listen to the reasoning of your legislators.

# ivolvement egional heme

Don't help your legislators when they seek your assistance from time to time. They were elected and are, after all, being paid to represent you. If they ask for information, opinions, advice, or guidance procrastinate or ignore their request.

Use every opportunity to belittle the importance of your legislators. Of course, they're making decisions that affect your life and capacity to pursue your business profitably, but to admit that might require you to change your whole approach to the way you deal with public officials.

Never invite your legislators to your home, your club, or your place of business. It is possible they may become familiar with some of your problems and initiate legislative action to remedy them.

Never recognize that legitimate differences of opinion exist and that legislators get pressures from many conflicting and opposing interests. Insist that he be with you 100%, all of the time regardless of other pressures.

Be sure to stay uninformed about the legislative issues that affect you and your business. Be sure you know so little about the issues that you can't discuss them with your legislators. Ignore the newsletters that come from trade associations like the Maryland Bankers or the Chamber of Commerce. They give you facts that might confuse you.

If you ever communicate with legislators don't take the trouble to express your reasons in your own words. Use form letters, they're far less effective, particularly postcards which don't have to be opened and carry a shorter message with no room for listing reasons why legislators should vote your way on a bill.

At a social affair avoid serious discussion of vital issues with legislators. So what if you miss an opportunity. There are plenty of other things to discuss that are more fun.

In testifying or in direct personal contacts with legislators stretch the truth if it serves your need. Legislators are accustomed to duplicity and they admire skillful truth dodgers. Besides they have short memories and tomorrow on another bill it's a whole new ball game.

Don't waste your time studying the bill. The legislators probably haven't read it so it's unlikely they'll catch you with harmful questions.



Mr. John Sargeant, Executive Director of the Medical and Chirurgical Faculty of Maryland outlined the health care legislation which is likely to arise in the next session of the General Assembly.

If it's a technical subject confound them with specialized terms and multi-syllabic words. They'll be impressed with your knowledge and won't dare to show their ignorance by voting against you.

Hit hard at your opponents. Ridicule their arguments. Question their motives. Such tactics are believed to pay dividends in a courtroom and there is no reason to believe legislators are any different than jurors.

Don't hesitate to show your displeasure toward committee members who ask antagonistic questions. The other committee members will be more inclined to sympathize with you if you strike back.

Of course, you'll recognize this final contribution I've made today as an attempt to dramatize the wrong way to go in legislative relations. Please don't follow that blueprint. It is a sure way to lose friends and influence no legislators at all.

Thank you.

DECEMBER, 1978

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# Lilly Digest Results for 1977

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During 1977, total sales continued to improve in the community pharmacies that reported their operating data to the Lilly Digest (Table 1). The growth rate was once again lower than the average annual rate of 6.4 percent set over the past decade. Although total sales showed a favorable increase, the cost of goods sold rose at a faster rate and thereby left a smaller gross margin than in previous years. Total expenses stabilized at 31.5 percent of sales (the same as in 1976), in spite of a decline in proprietor's or manager's salary as a percent of sales, but net profit dropped to an all-time low of 3.4 percent.

An average sales volume of \$322,755 was recorded by community pharmacies, which represents an increase of 4.2 percent over the 1976 average. It should be noted that this rate of growth is considerably lower than the 5.4 percent one-year growth rate observed during 1976. Table 2 shows prescription sales of the 1,712 participating pharmacies continuing their upward advance to 50.4 percent of total sales as compared with 49.6 percent for

other sales. The amount of prescription sales has also climbed at a faster rate (5.8 percent) than other sales (2.6 percent). This upward trend in prescription sales has continued for more than 20 years. The importance of the professional area to the average community pharmacy cannot be overemphasized.

The 1978 Lilly Digest shows another rise in the cost of goods sold — from 64.9 to 65.1 percent of sales in 1977. As a result, gross margin dropped to 34.9 percent — its lowest level in 20 years. This means that, during 1977, community pharmacies had a lower percentage of the sales dollar to cover total expenses and provide for an adequate net profit.

With a lower gross margin to cover operating costs, total expenses must be reduced percentagewise if net profit before taxes is to remain stable. Unfortunately, even though the proprietor's salary declined from 7.3 to 7.0 percent of sales in 1977, it was not enough to lower total expenses as a percent of sales. They remained un-

TABLE 1 Current trends in pharmacy operations			
AVERAGES PER PHARMACY	1977	1976	Amount and
AVERAGES FER FRARMACT	1,712 Pharmacies	1,705 Pharmacies	Percent of Change
Total sales Cost of goods sold	\$322,755 — 100.0% 209,945 — 65.1%	\$309,725 — 10 <b>0</b> .0% 200,871 — 64.9%	+\$13,030 — .42% +\$ 9,083 — 4.5%
Total sales Cost of goods sold	\$322,755 — 100.0% 209,954 — 65.1%	\$309,725 — 100.0% 200,871 — 64.9%	+\$13,030 — 4.2% +\$ 9,083 — 4.5%
Gross margin Expenses	\$112,801 — 34.9%	\$108,854 — 35.1%	+\$ 3,947 — 3.6%
Proprietor's or manager's salary Employees' wages Rent Heat, light, and power Accounting, legal, and other professional fees Taxes (except on buildings, income,	\$ 22,622 — 7.0% 38,063 — 11.8% 8,080 — 2.5% 2,874 — 0.9% 1,464 — 0.5%	\$ 22,597 — 7.3% 36,417 — 11.8% 7,758 — 2.5% 2,650 — 0.9% 1,377 — 0.4%	+\$ 25 — 0.1% +\$ 1,646 — 4.5% +\$ 322 — 4.1% +\$ 224 — 8.4% +\$ 87 — 6.3%
and profit) and licenses Insurance (except on buildings) Interest paid Repairs Delivery Advertising Depreciation (except on buildings) Bad debts charged off Telephone Miscellaneous	4,855 — 1.5% 3,365 — 1.0% 1,830 — 0.6% 1,122 — 0.3% 1,430 — 0.4% 3,772 — 1.2% 2,655 — 0.8% 429 — 0.1% 1,178 — 0.4% 8,039 — 2.5%	4,574 — 1.5% 2,897 — .09% 1,734 — 0.6% 1,055 — 0.3% 1,393 — 0.4% 3,633 — 1.2% 2,522 — 0.8% 448 — 0.1% 1,119 — 0.4% 7,670 — 2.4%	+\$ 281 — 6.1% +\$ 468 — 16.1% +\$ 96 — 5.5% +\$ 67 — 6.3% +\$ 139 — 3.8% +\$ 139 — 3.8% -\$ 19 — 4.2% +\$ 59 — 5.3% +\$ 369 — 4.8%
Total expenses	\$101,778 — 31.5%	\$ 97,844 — 31.5%	+\$ 3,934 — 4.0%
Net profit (before taxes) +\$ 13 0.19	\$ 11,023 — 3.4%	\$ ,010 — 3.6%	
Total income of self-employed proprietor (before taxes on income and profits) Value of inventory at cost Annual rate of turnover of inventory Hours per week pharmacy was open	\$ 33,645 — 10.4% \$ 53,382 — 16.5% 4.0 times 65	\$ 33,607 — 10.9% \$ 51,008 — 16.5% 4.1 times 65	+\$ 38 — 0.1% +\$ 2,374 — 4.6% No change

changed from the previous year's data at 31.5 percent of sales. Therefore, net profit declined to 3.4 percent of sales during 1977.

As a percent of sales, rent has remained constant at 2.5 percent — a figure that has not been altered for over a decade.

Miscellaneous operating expenses (representing all expenses other than proprietor's or manager's salary, employees' wages, and rent) were higher as a percent of sales and now stand at 10.2 percent for the first time since 1972 (up from 9.9 percent in 1976). Increases among the miscellaneous operating expenses offset the decline in the proprietor's salary category and accounted for the unchanged total expense figure.

Although total prescription sales were greater dollarwise, the average number of prescriptions dispensed decreased for the second consecutive year. There were 26,649 total prescriptions in 1977 — down 514 from the previous year's figure. The higher pre-

TABLE 2 Current trends in prescription department of	1977	1976	Amount and
AVERAGES PER PHARMACY	1,712 Pharmacies	1,705 Pharmacies	Percent of Change
Sales			
Prescription	\$162,631 50.4%	\$153,735 — 49.6%	+\$ 8,896 - 5.8%
Other	160,124 — 49.6%	155,990 — 50.4%	+\$ 4,134 2.6%
Total	\$322,755 — 100.0%	\$309,725 — 100.0%	+\$13,030 4.2%
Value of inventory at cost and	***************************************		
as a percent of sales			
Prescription	\$ 19,471 — 12.0%	\$ 18,554 12.1%	+\$ 917 4.9%
Other	33,911 — 21.2%	32,454 — 20.8%	+\$ 1,457 — 4.5%
Total	\$ 53,382 — 16.5%	\$ 51,008 — 16.5%	+\$ 2,374 — 4.6%
Sales per dollar invested in inventory			4 000 070
Prescription	\$8.35	\$8.29	+\$ 0.06 — 0.7%
Other	4.72	4.81	-\$ 0.09 — 1.9%
Size of area (square feet)*	371 — 14.8%	368 — 15.0%	+ 3 — 0.8%
Prescription Other	2,131 — 85.2%	2.089 — 85.0%	+ 42 — 2.0%
	2.502 — 100.0%	2.457 — 100.0%	+ 45 - 1.8%
Total Sales per square foot*	2,502 — 100.076	2,457 — 100.076	+ 45 1.0%
Prescription	\$439.27	\$414.54	+\$ 24.73 — 6.0%
Other	75.94	74.92	+\$ 1.02 - 1.4%
Total	129.85	125.73	+\$ 4.12 3.3%
Number of prescriptions dispensed			
New	12,931 — 48.5%	12,860 — 4.73%	+ 71 - 0.5%
Renewed	13,718 — 51.5%	14,303 — 52.7%	- 585 — 4.1%
Total	26,649 — 100.0%	27,163 — 100.0%	- 514 - 1.9%
Prescription charge	\$6.10	\$5.66	+\$ 0.44 7.8%
*Based on averages of pharmacies that reported all data			

NOTE: These national averages are presented to give a composite picture of the average LILLY DIGEST pharmacy. Comparisons for analysis should be based on the operations of pharmacies of comparable sales and prescription size which appear in one of the 34 arrangements in the "Heart of the LILLY DIGEST."

scription revenue resulted from the 44-cent rise in the average prescription charge, from \$5.66 to \$6.10. Again, as in years past, the size of the average prescription (the number of doses dispensed) increased and now stands at 138.3 (1967 = 100). The upward trend in new prescriptions as a percentage of the total dispensed continued during 1977 (from 47.3 to 48.5 percent) and may be attributed to additional federal and state regulations, third-party program requirements, and inroads by new competitors, especially in regard to prescriptions for chronic medication.

Net profit, before taxes, was essentially unchanged dollarwise. However, when expressed as a percent of sales, it fell to 3.4 percent. The decline in both net profit and proprietor's salary caused total income for the proprietor to drop substantially as a percent of total sales, from 10.9 percent in 1976 to 10.4 percent in 1977, even though, in dollars, total income was about the same at \$33,645.

Total inventory increased in dollars to \$53,382 in the past year; however, as a percent of sales, it remained stable at 16.5 percent. Although prescription inventory went up slightly dollarwise, it declined as a percent of sales to 12.0 percent, down from 12.1 percent in 1976. Other merchandise was higher in terms of both dollars and percentage of sales as it rose from 20.8 to 21.2 percent. This relationship allowed the sales productivity of the professional department (prescription revenue per prescription inventory dollar) to increase from \$8.29 to \$8.35, whereas the productivity of other departments declined from \$4.81 to \$4.72.

For the first time, the prescription area brought in the majority of all sales dollars in the average community pharmacy. Management should insure that this current growth is maintained and also attempt to strengthen sales in other merchandise areas.

Averages per Pharmacy	1977 SOUTH ATLANTIC STATES (230 Pharmacies)	1976 SOUTH ATLANTIC STATES (216 Pharmacies)	1977 UNITED STATES AVERAGE (1,712 Pharmacies)
Sales Prescription Other Total	\$ 169,080 — 55.2% 137,473 — 44.8% \$ 306,553 — \$100.0%	54.0% 46.0% \$328.052 — 100.0%	50.4% 49.6% \$322.755 — 100.0%
Cost of goods sold	198.152 — 64.6%	64.3%	65.1%
Gross margin	\$ 108,401 — 35.4%	35.7%	34.9%
Expenses Proprietor's or manager's salary Employees' wages Rent Miscellaneous expenses Total expenses	\$ 23,509 — 7.7% 36,254 — 11.8% 7,306 — 2.4% 30,462 — 10.0% \$ 97,531 — 31.9%	7.3% 12.5% 2.2% 10.1% 32.1%	7.0% 11.8% 2.5% 10.2% 31.5%
Net profit (before taxes)	\$ 10,870 — 3.5%	3.6%	3.4%
Total income of self-employed proprietor (before taxes on income and profits)	\$ 34,379 11.2%	10.9%	10.4%
Value of inventory at cost and as a percent of sales Prescription Other Total	\$ 20,018 — 11.8% 29,060 — 21.1% \$ 49,078 — 16.0%	12.1% 20.7% 16.0%	12.0% 21.2% 16.5%
Annual rate of turnover of inventory	4.2 times	4.1 times	4.0 times
Number of prescriptions dispensed New Renewed Total	13,715 — 47.3% 15,304 — 52.7% 29,019 — 100.0%	45.9% _54.1% 100.0%	. 48.5% . 51.5% 100.0%
Prescription charge	\$ 5.83	\$ 5.44	\$ 6.10
Number of hours per week Pharmacy was open Worked by proprietor Worked by employed pharmacist(s)	63 hours 48 hours 31 hours	67 hours 51 hours 42 hours	65 hours 46 hours 34 hours

### Lilly Hospital Pharmacy Survey

Key operating data were arranged to reflect a composite picture of the "average" hospital pharmacy in the United States for 1977 (Table 1). It is important to realize that this hypothetical pharmacy is derived mathematically from a wide range of operating data; therefore, the figures are perhaps too general to be used for the purpose of comparison. However, the data can be analyzed for the determination of trends by comparing them with similar data from last year's Survey, which measured 1975 operations. The comparison shows that the average hospital had a bed capacity of 270 in 1977 as compared with 258 in 1975. Census remained unchanged at 74 percent; however, admissions increased to 10,008-up from 9087-which resulted in a shorter period of patient stay-7.3 days.

Once again, this year's SURVEY shows the average class of hospital reporting to be private (nonprofit). Furthermore, the average profile was that of a general institution which treats a variety of illnesses and offers routine and relatively uncomplicated surgery procedures.

The number of hours worked by pharmacists and technicians and the hours the main pharmacy was open increased during the two-year period, 1975 to 1977. It is interesting to note that, even though the pharmacy was open almost 7 percent longer during 1977, pharmacist hours increased 23 percent and technician hours rose 40 percent. Overall, 2.4 hours of pharmacist time and 2.3 hours of technician time were required for each hour the pharmacy was open during 1977.

Although inventory and purchases levels were higher during 1977, the estimated inventory turnover rate showed a distinct improvement—up to 5.1 from 4.7 times in 1975. Inventory rose 11.7 percent during 1977 as compared with the 1975 figure, and purchases increased 20.6 percent. On a per-bed basis, inventory and purchases were larger even though the average bed capacity in

1977 was higher (up to 270 from 258 in 1975).

However, since these figures do not take inflation into account, the dollar amounts shown do not necessarily reflect expanded usage of drugs and related items by hospital patients.

The main hospital pharmacy floor area averaged 1476 square feet in

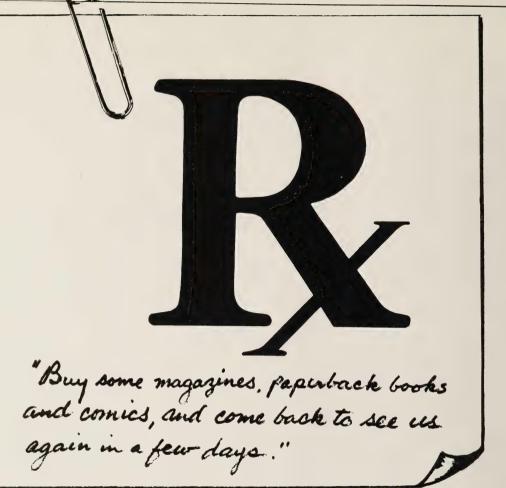
this edition of the SURVEY.

Data pertaining to services furnished by hospital pharmacies are tabulated in this year's SURVEY. Of the 13 listed, the following were offered on a daily basis by over 50 percent of those reporting—monitoring patient profiles, monitoring drug interactions, preparing I.V. fluids, and providing drug information services.

Table 1 AVERAGE HOSPITAL PHARMACY (2120 hospitals reporting 1977 annual data)

1977	1975	Percent of Change
Bed capacity 270 Class Private	258 Private (nonprofit) n/a	+ 4.7%
Census (beds occupied) 74%  Admissions 10,008  Length of patient	74% 9087	+10.1%
stay 7.3 days  Hours pharmacy	7.7 days	. 0.00/
open/week 79 Days main pharmacy	74	+ 6.8%
open/week 6 Pharmacist	n/a	
hours/week 187 (4.7 FTE)* Technician	152 (3.8 FTE)*	+23.0%
hours/week 180 (4.5 FTE)* Inventory \$76,681 \$1.05/Patient day \$ 284/Bed \$ 384/Occupied bed \$7.66/Admission	129 (3.2 FTE)* \$68,648 \$0.98/Patient \$ 266/Bed \$ 360/Occup \$7.55/Admiss	ied bed sion
Purchases \$392,470 \$ 5.37/Patient day \$1,453/Bed \$1,964/Occupied bed \$39.21/Admission	\$325,409 \$ 4.65/Patien \$1,261/Bed \$1,705/Occu \$35.81/Admi	pied bed
Formulary Yes Estimated inventory	Yes	
turnover rate 5.1 times Floor area 1476 sq ft Services offered by over 50%	4.7 times n/a	
of pharmacies Monitoring patient profiles Monitoring drug interactions Preparing I.V. fluids Providing drug information service	n/a es	

<sup>\*</sup>FTE = Full-time equivalent based on a 40-hour week.



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Get on the bandwagon. Call Phil Appel today at: The Maryland News Distributing Co. (301) 233-4545 Geigy announces a new age in beta blockade

New

### **Lopressor**

metoprolol tartrate

A significant advance in the treatment of hypertension



Please turn page for brief summary of prescribing information.

## New Lopressor<sup>™</sup>

metoprolol tartrate

Lopressor™ brand of metoproiol tartrate

An antihypertensive beta-blocking agent

Indications Lopressor, brand of metoprolol tartrate, is indicated in the management of hypertension. It may be used alone or in combination with other antihypertensive agents, especially thiazide-type diuretics

Contraindications Lopressor, brand of metoprolol tartrate, is contraindicated in sinus bradycardia, heart block greater than first degree, cardiogenic shock, and overt cardiac failure (see Warnings)

Warnings Cardiac Failure: Sympathetic stimulation is a vital component supporting circulatory function in congestive heart failure, and beta blockade carries the potential hazard of further depressing myocardial contractility and precipitating more severe failure. In hypertensive patients who have congestive heart failure controlled by digitalis and diuretics, Lopressor, brand of metoprolol tartrate, should be administered cautiously. Both digitalis and metoprolol slow AV conduction.

In Patients Without a History of Cardiac Failure continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, patients should be fully digitalized and/or be given a diuretic, and the response observed closely. If cardiac failure continues, despite adequate digitalization and diuretic, Lopressor, brand of metoprolol tartrate. therapy should be withdrawn.

Ischemic Heart Disease: Following abrupt cessation of therapy with certain beta-blocking agents, exacerbations of angina pectoris and, in some cases, myocardial infarction have been reported. Even in the absence of overt angina pectoris, when discontinuing therapy, Lopressor, brand of metoprolol tartrate, should not be withdrawn abruptly, and patients should be cautioned against interruption of therapy without the physician's

Bronchospastic Diseases: PATIENTS WITH BRON-CHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Because of its relative beta, selectivity, however, Lopressor, brand of metoprolol tartrate, may be used with caution in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment. Since beta, selectivity is not absolute, a beta2 -stimulating agent should be administered concomitantly and the lowest possible dose of metoprolol should be used. It may be prudent initially to administer metoprolol in three doses daily, instead of two, to avoid the higher plasma levels associated with the longer dosing interval. (See Dosage and Administration.)

Major Surgery: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Metoprolol, like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g. dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in restarting and maintaining the heart beat has also been reported with beta blockers.

Diabetes Mellitus: Beta-adrenergic blockade may mask symptoms of hypoglycemia (e.g., tachycardia) and may potentiate insulin-induced hypoglycemia.

Lopressor, brand of metoprolol tartrate, should therefore be used with caution in diabetic patients, especially those with labile diabetes

### The relatively selective beta blocker with b.i.d. dosage for hypertension

Thyrotoxicosis: Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyper thyroidism. Patients suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrawal of beta blockade which might precipitate a thyroid storm

Precautions Impaired Henatic or Renal Function: The drug should be used with caution in patients with impaired hepatic or renal function.

Drug Interactions: Catecholamine-depleting drugs (e.g., reserpine) may have an additive effect when given with beta-blocking agents. Patients treated with Lopressor, brand of metoprolol tartrate, plus a catecholamine depletor should therefore be closely observed for evidence of hypotension and/or marked bradycardia which may produce vertigo, syncope, or postural hypotension.

Long-Term Animal Studies: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In a one-year study in dogs, there was no evidence of drug-induced toxicity at or below oral doses of 105 mg/kg per day. Two-year studies in rats at three oral dosage levels of up to 800 mg/kg per day did not indicate an increase in the development of spontaneously occurring benign or malignant neoplasms of any type. The only histologic changes which appeared to be drug-related were an increased incidence of generally mild focal accumulation of foamy macrophages in pulmonary alveoli and a slight increase in biliary hyperplasia. Neither finding represents symptoms of a known disease entity in man. In a 21-month study in mice at three oral dose levels of up to 750 mg/kg per day, benign lung tumors (small adenomas) occurred more frequently in female mice receiving the highest dose than in untreated control animals. There was no increase in malignant lung tumors or total (benign plus malignant) lung tumors. The overall incidence of tumors or malignant tumors was also unaffected by metoprolol administration

Usage in Pregnancy: Reproduction studies in animals did not reveal any evidence of impaired fertility or of teratogenic potential. There was evidence in the rat of increased postimplantation loss and decreased neonatal survival (threshold between 50 and 500 mg/ kg). Distribution studies in mice confirm exposure of the fetus when metoprolol is administered to the pregnant animal. There are no well-controlled studies in pregnant women. Lopressor, brand of metoprolol tartrate, should be used in pregnant women only when clearly needed.

Nursing Mothers: It'is not known whether this drug is excreted in human milk. Since most drugs are excreted in human milk, nursing should not be undertaken by mothers receiving metoprolol

Usage in Children: Safety and effectiveness in children

Adverse Reactions Most adverse effects have been mild and transient

Central Nervous System: Tiredness and dizziness have occurred in about 10 of 100 patients. Depression was reported in about 5 of 100 patients. Headache nightmares, and insomnia have also been reported but drug relationship is not clear.

Cardiovascular: Shortness of breath and bradycardia have occurred in approximately 3 of 100 patients. Cold extremities, Raynaud's disease, palpitations and congestive heart failure have been reported. See Contraindications, Warnings, and Precautions.

Respiratory: Wheezing (bronchospasm) has been reported in less than 1 of 100 patients. See Warnings.

Gastrointestinal: Diarrhea has occurred in about 5 of 100 patients. Nausea, gastric pain, constipation, flatulence, and heartburn have been reported in 1 of 100 or Allergic: Pruritus has occurred in less than 1 of 100

Miscellaneous: Peyronie's disease has been reported in less than 1 of 100,000 patients

The oculomucocutaneous syndrome associated with the beta blocker practolol has not been reported with Lopressor, brand of metoprolol tartrate, during investigational use and foreign marketing experience.

Potential Adverse Effects: In addition, a variety of adverse effects not listed above have been reported with other beta-adrenergic blocking agents, and should be considered potential adverse effects of metoprojol.

Central Nervous System: Reversible mental depression progressing to catatonia; visual disturbances: hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Cardiovascular: Intensification of AV block (see Contraindications)

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura

Allergic: Erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory

Miscellaneous: Reversible alopecia.

Clinical Laboratory Test Findings: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase

Dosage and Administration Dosage of Lopressor, brand of metoprolol tartrate, should be individualized. The usual initial dose is 50 mg twice daily whether used alone or added to a diuretic. The dosage may be in creased at weekly (or longer) intervals until optimum blood pressure reduction is achieved. In general, the maximum effect of any given dosage level will be apparent after one week of therapy. Usual maintenance dosage is approximately 100 mg twice a day, with a range of 100 to 450 mg per day. Dosages above 450 mg per day have not been studied. While twice-daily dosing is effective and can maintain a reduction in blood pres sure throughout the day, some patients, especially when lower dosages are used, will experience a modest rise in blood pressure toward the end of the 12-hour dosing interval. This can be evaluated by measuring blood pressure near the end of the dosing interval to deter mine whether satisfactory control is being maintained throughout the day. If control is not adequate, a larger dose, or three times daily therapy, may achieve better control. Beta, selectivity diminishes as dosage of Lopressor, brand of metoprolol tartrate, is increased

This drug should be stored at controlled room temperature and protected from moisture

How Supplied Tablets of 50 mg (capsule-shaped, scored, light red, film-coated) and 100 mg (capsuleshaped, scored, light blue, film-coated) are supplied in bottles of 100 and 1,000 and Unit Dose Packages of 100.

Store at controlled room temperature and protect from 667290 (8/78) C78-38

Before prescribing or administering, please consult complete product information.

Manufactured by: CIBA-GEIGY Canada Ltd. Dorval, P.Q. Canada H9S1B1 Distributed by: GEIGY Pharmaceuticals Division of CIBA-GEIGY Corporation Ardsley, New York 10502

Geigy

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Leonard DeMino, outgoing President of the Prince George-Montgomery County Pharmaceutical Association, evaluated the Association's accomplishments during the previous year.



The Officers and Executive Committee of the Association are installed at Mr. Ho's Restaurant in Gaithersburg.

# Prince George-Montgomery County Pharmaceutical Association Installs New Officers at Annual Banquet



Mr. Stanley Brown, the Incoming President of the Association addresses the banquet. The affair was held on November 5, 1978.



Mr. Paul Reznek, Secretary-Treasurer of the PG/MC Association and Honorary President of the Maryland Pharmaceutical Association, acted as toastmaster for the event.

# Shoplifting: a battle we can't afford to lose



# SHOPLIFTING FACTS & FIGURES

- 1. U.S. shoplifting losses will run more than \$7 billion during 1978
- About 4 million shoplifters are apprehended each year

   about one every 18 seconds.
- Stores across the country spend more than \$4 billion a year for security programs.
- The average value of items stolen is now \$28. A few years ago it was \$2.
- 5. Large city surveys indicate one of every 12 customers is a shoplifter.
- An average of 2-3% of sales volume is lost to shoplifting; individual store losses range from 1.7% to as high as 10% and is a significant factor in some branch closings and corporate bankruptcies.
- Shoplifting is currently costing the hard-pressed consumer between 10-15¢ on each dollar spent, according to a recent Massachusetts report.
- No area is immune. Studies show that it is an urban, suburban and rural problem.
- Over 50% of all shoplifting apprehensions involve the 13 to 19 age group.
- 10. Girl shoplifters outnumber boys 20 to 1.
- Approximately 45% of all shoplifting losses takes place during the Christmas shopping season, followed by the "back to school" period.
- Fridays and Saturdays are the shoplifters' busiest days; opening, closing and lunch hours are the most vulnerable times.

# MARYLAND LIABILITY FOR ACTS BY CHILDREN

Section 3-829

Courts and Judicial Proceedings

Annotated Code of Maryland as amended by the 1977 Session of the General Assembly — Effective July 1, 1977

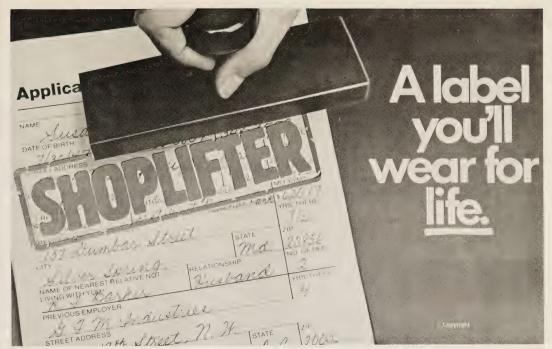
#### Chapter 30

hearing for the child.

(a) In any case in which the court finds that a child has, wilfully or maliciously, either (i) stolen, damaged, or destroyed the property of another, or (ii) inflicted personal injury on another, requiring the injured person to incur medical, dental or hospital expenses, the court may enter a judgment of restitution to the wronged person against the parent or parents of the child.

- (b) A judgment rendered under this section may not exceed (1) As to property stolen or destroyed, the fair market value of
- the property or \$5,000.
  (2) As to property damaged, the amount of damage not to
- exceed the fair market value of the property damaged or \$5,000.
  (3) As to personal injuries inflicted, the reasonable medical, dental, and hospital expenses incurred by the injured person as a
- result of the injury or \$5,000.

  (c) A judgment of restitution against a parent may not be entered unless the parent has been afforded a reasonable opportunity to be heard and to present appropriate evidence in his behalf. A hearing under this section may be held as part of a disposition
- (d) The judgment may be enforced in the same manner as enforcing monetary judgments.
- (e) The court may order the child who, wilfully or maliciously steals, damages, or destroys the property of another or inflicts personal injury on another to make the restitution expenses himself if that is feasible considering the age and circumstances of the child; and if this is ordered, the liability of the child precedes the liability of the parent. The court may, in the alternative, enter a judgment or restitution against the child.



The Maryland Retail Merchants Association used posters like this during its recent anti-shoplifting campaign in Maryland.

### MARYLAND SHOPLIFTING LAW

The Annotated Code of Maryland as of July 1, 1977 Article 27 Section 551 A. Shoplifting

(a) WHAT CONSTITUTES. — In any mercantile establishment, it

is unlawful for any person
(1) To remove any goods, wares or merchandise from the immediate place of display or from any other place within the establishment with the intent to appropriate the same to the use of the personso taking, or to deprive the owner of the use, or value, or any part thereof; or

(2) To obtain or attempt to obtain possession of any goods, wares or merchandise, by charging the same to a real person without the authority of such person, or to a fictitious person, with a like intent; or.

(3) To conceal any such goods, wares or merchandise with a like intent; or,

(4) To alter, remove, or otherwise disfigure any label or price tag with a like intent; or,

(5) To transfer any goods, wares or merchandise from a container in which the same shall be displayed or packaged to any other container with a like intent; and any person committing any of the acts mentioned is guilty of shoplifting.

(b) AIDING OR ABETTING. — Any person who aids or abets in the commission of the acts set out in subsection (a) is guilty of

(c) CIVIL LIABILITY FOR DETENTION OR ARREST. — A merchant or an agent or employee of the merchant who detains or causes the arrest of any person shall not be held civilly liable for detention, slander, malicious prosecution, false imprisonment, or

false arrest of the person detained or arrested, whether the detention or arrest takes place by the merchant or by his agent or employee, if in detaining or in causing the arrest of the person, the merchant or the agent or employee of the merchant had at the time of the detention or arrest probable cause to believe that the person committed the crime of shoplifting as defined in this section.

(d) PENALTY. — Every person convicted of the crime of shopliting to the value of \$100 or upwards, or as accessory thereto before the fact, is guilty of a felony and shall restore any goods, or things taken, to the owner or shall pay him their full value and shall be fined not more than \$1,000 or be imprisoned in the penitentiary for not more than three years. If any person is convicted of the crime of shoplifting under the value of \$100, he is guilty of a misdemeanor and shall restore the goods and chattels taken, or pay their full value to the owner thereof, and be fined not more than \$500 or imprisoned for not more than 18 months in the house of correction or jail, or both fined and imprisoned.

(e) SEVERABILITY. — If any part, section, paragraph, clause, sentence, or provision of this section shall be held invalid for any reason, the remainder of this section, or other applications thereof, shall not be affected thereby, and to this end, the provisions of this section are declared severable.

(f) SECTION ADDITIONAL TO OTHER PROVISIONS. — This section is declared to be in addition to any other criminal provision heretofore existing in this State.

(g) REPEAL OF INCONSISTENT PROVISIONS. — All laws, or parts of laws, inconsistent with the provisions of this section are hereby repealed to the extent of the inconsistency.

(h) ACTIONS ACCRUING PRIOR TO JUNE 1, 1961. — Nothing in this section shall affect any cause of action which has accrued prior to June 1, 1961.

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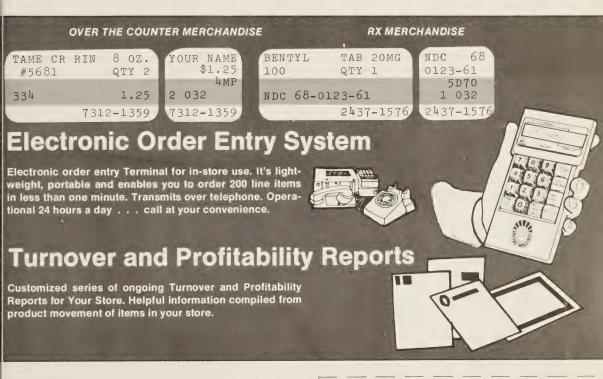
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- Customized Pricing.
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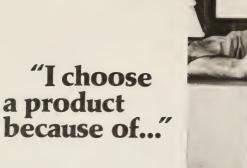
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### Lamy discusses elderly at ME Conference

"Although approximately 85 percent of elderly patients take prescription medications, there is no comprehensive body of knowledge on medicines and aging, so physicians have no real prescribing guidelines," Dr. Peter P. Lamy, Professor and Director of the Institutional Pharmacy Program at the University of Maryland School of Pharmacy, recently told participants in a Washington, D.C., conference on "Medication Management and Education of the Elderly," held by Excepta Medica under a grant from Roche Laboratories, Division of Hoffmann-La Roche Inc.

Dr. Lamy's suggestions and those of the other leading physicians and pharmacists attending the symposium are being used in the Medication Education (ME) program, a nationwide public service effort underwritten by Roche Laboratories, and designed to help educate patients about the proper use of the medicines they must take.

"The fact that persons living to be 65 can now expect to live another 20 years, and that the elderly are more prone than any other age group to respond to drug therapy with unexpected side effects, has created an urgent need for the development of specific therapeutic guidelines," Dr. Lamy said.

"Many misconceptions about the elderly exist today including the concept that the term 'elderly' can be determined by chronological age alone," Dr. Lamy said.

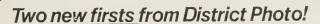
"Actually, the physiological and pathological status of an individual is a much more significant determination of age. The elderly are not a homogeneous group."

Another prominent misconception about the elderly is that all older people tend to become helpless. "In fact," Dr. Lamy said, "80 percent of the elderly are healthy enough for normal activities and only about 5 percent are house- or bed-bound.

"As disease alters the normal functions of the body, disease can also alter the body's response to drug therapy, particularly in the elderly. The development of a model of health care for the elderly is urgent," Dr. Lamy said. "While knowledge of drugs is important, it is equally important for physicians to seek patient cooperation and compliance if errors in usage are to be avoided.

"In prescribing for the elderly it is most important to discuss the treatment plan with the patient," Dr. Lamy said. "In this way, compliance is more likely to be achieved because the patient will understand and agree to the treatment plan. Also the therapy should be planned for a predetermined duration, reviewed periodically and altered if necessary."

The United States allocates proportionately more resources to the aged than any other nation in the Western world. "Yet results in terms of health status of older persons are unsatisfactory," Dr. Lamy said.



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# The straighter they talk, the better things get.

### Meet our 1978 Pharmacy Consultant Panel.



Fred M. Eckel, R.Ph., Assoc. Professor of Hospital Pharmacy Chapel Hill, N.C.



Donald A. Dee, R.Ph., Exec. Sec. Minnesota Pharmaceutical Assoc Minneapolis, Minnesota



John Spicer, R.Ph. Community Pharmac Fowler, Michigan



Benjamin F. Cooper, Ph.D., Dean, School of Pharmacy Auburn University, Auburn, Ala



Don F. Gould, R.Ph., Chairman of the Board, Gould Drug Company Mt. Pleasant, Michigan



Arthur Koorhan, R.Ph., Div. V.P. Pharmacy Operations, Cunningham Drug Stores, Detroit, Michigan



Nelson E. Taylor, R.Ph Community Pharmacis



Community Pharmacist Gladewater, Texas



David Zilz, R.Ph., Dir. Pharmacy and Central Service, University of Wisconsin Hospitals Madison Wisconsin



Don W. Arthur, R.Ph Community Pharmacist Buffalo New York

These days, any company that depends on "yes" men for advice is riding for a fall.

At Upjohn, the views of pharmacy are important to us.

These ten leaders on our 1978 Pharmacy Consultant Panel have provided us with an invaluable service.

They provide their views on a variety of matters - professional and operational - giving us their candid opinions.

For this, we are sincerely grateful. Upjohn



### HOW IT CAN HURT A HYPERTENSIVE

What happens when a person lights up a cigarette? And if he does so often, what can that tell us about his blood pressure? In an effort to answer these burning questions, investigators have probed the physiology of smoking.

The physiological truth

According to a report in the New England Journal of Medicine,1 two major hazards of cigarette smoke are its carbon monoxide and nicotine components. Carbon monoxide promotes the development of atherosclerotic-like lesions in vessels and decreases the amount of oxygen available to the myocardium.

Nicotine proves to be an agent capable of directly stimulating sympathetic ganglions and the adrenal medulla, causing subsequent release of catecholamines from both chromaffin tissue and sympathetic nerve endings. Two of the catecholamines released are epinephrine and norepinephrine. Cryer et al<sup>2</sup> report that elevations of these specific catecholamines occur within 10 minutes of the start of smoking. Along with them, "Significant increments in pulse rate, systolic and diastolic blood pressure, blood glyceryl and blood lactate/pyruvate ratio also occurred.

As Lefkowitz points out, however, a key question arising from this chain of events is "Do pulse and blood pressure remain elevated or do they return to normal....?

58 years of observation

One attempt at answering this came from Dr. Alton Ochsner's 58 years of study of cardiovascular patients. He agrees that tobacco exerts a number of deleterious vascular effects, including severe spasms of the arterioles, which decrease the blood flow through the arteriolar system and capillary bed. He says: "Nicotine, which is the culprit in the production of cardiovascular disease, also increases the blood levels of free fatty

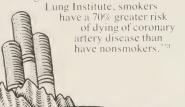
terol, which favor arteriosclerosis."3

But most importantly, Dr Ochsner observed that smokers had higher blood pressure levels than nonsmokers and higher mortality rates at corresponding blood pressure levels. Other studies are at variance with this finding, but do concur with Dr. Ochsner that here is yet another telling link between smoking and hypertension.

The important link

It is cardiovascular disease. *Science* reports<sup>4</sup> "Cigarette smoking has repeatedly been shown to substantially increase the risk of cardiovascular disease, and there is some evidence that those who stop smoking may decrease their risk.

Ochsner further states: "According to the National Heart and



"Also, eigarette smoking is associated with a disproportionately high incidence of sudden death, and a higher incidence of strokes.

Thus, rather than causing hypertension, smoking may influence the incidence of cerebrovascular accidents and attendant mortality. (Ochsner found attendant mortality to be 2.3 times greater among smokers than nonsmokers.3)

Heart disease is the most common cause of death in our population<sup>5</sup> and coronary arteriosclerosis is often its cause.5 Smoking is a risk factor for coronary heart disease, as is hypertension. Thus the hypertensive who smokes, or the smoker who becomes a hypertensive, is greatly increasing his risk of coronary artery disease.

With this in mind, Dr. Norman Kaplan counsels his smoking patients with the following: "...it will be to your advantage to quit. If you stop smoking you'll have a 50% less chance of having a heart attack, and if you have one, about 70% less chance of dying from it. ... smoking. along with hypertension and high cholesterol, are the three main controllable factors causing heart attacks.

Your patients may benefit from the same advice.

Lefkowitz RJ. Smoking, catecholamines and the

. Cryer PE. Haymond MW Santiago JV. et a

### 295 573-577. September 9. 1976

September 1976 Sentember 1976
4 Kolata GB Marx JL. The epidemiology of heart disease. Searches for causes. Science 194 509
512. October 29: 1976
5 Smoking and Health US Department HFW Publi-Health Service. 1964 chap 11
6 Kaplan NM Your Blood Press.



acids and choles

# ACA Announces Publication on Drug Interactions

The American College of Apothecaries is pleased to announce the availability of a new clinical self study course, *Independent Study Course in Drug Interactions*. This course, developed and written by Dr. Glen E. Farr, Pharm.D., Director of Clinical Affairs for the ACA, is designed to provide pharmacists and other health care professionals with information describing drug interactions. It is hoped that upon completion of this course the student will have a better understanding of the basic mechanisms of drug interactions as well as specific examples of many of the more significant drug interactions that occur.

The course consists of seven assignments, each with an examination, and is approved by the American College of Apothecaries for 30 contact hours or three Continuing Education Units (CEU's).

Each registrant for this course will receive a copy of *Drug Interactions*, Third Edition, by Philip D. Hansten, Pharm.D., for use as a reference text. Other texts and reference materials may also be utilized in answering the questions.

The American College of Apothecaries is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education #679-201.

This course is available for \$45.00 from the American College of Apothecaries, 874 Union Avenue, Memphis, Tennessee 38163.

### Making a Move ?

If you're moving, send us your new address 4 to 6 weeks ahead of time so your copy of MARYLAND PHARMACIST will keep up with you.

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### LETTERS



November 9, 1978

Mr. D. A. Banta Executive Director Maryland Pharmaceutical Association 650 West Lombard Street Baltimore, Maryland 21201

Dear Mr. Banta:

Effective September 5, 1978, the Marketing, Sales, and Administrative offices of Parke-Davis were moved to Morris Plains, New Jersey, and consolidated into the Pharmaceutical Division of the Warner-Lambert Company.

The official address has been changed to

PARKE-DAVIS Division of Warner-Lambert Company 201 Tabor Road Morris Plains, New Jersey 07950

and should be used for all purposes, excepting the following.

Correspondence or inquiries regarding credit matters or payment of invoices should be addressed to G.P.O. Box 118, Detroit, Michigan 48232.

Correspondence or inquiries concerning orders or other distribution matters should be addressed to the appropriate Parke-Davis Distribution Center.

Yours sincerely,

Marketing Communications Department

The Pharmaceutical Services Foundation has notified the MPhA of a change of address. The correct address is:

Box 10472

Baltimore, Maryland 21209

They can be reached at the following telephone number: (301) 466-1183.

### IR Committee Will Act As Ombudsman

The Industrial Relations Committee of the Maryland Pharmaceutical Association will act as an Ombudsman between a Pharmacist member and a manufacturing company when disputes arise. For additional information on this service, contact the MPhA office.



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Classified ads are a complimentary service for members.

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### Available From MPhA Office

Available free to members, notification form to be given to patient under drug product selection law. Call Sharon (301) 727-0746.

### - WANTED -

University of Maryland School of Pharmacy Alumni Association is looking for pharmaceutical antiques and memorabilia including old fixtures, bottles, advertisements and displays, small manufacturing equipment, mortars and pestles, antique soda fountain, pill tiles, patent medicines in original containers, etc. The items will be used in a recreation of an antique drugstore.

If you have information on where these things may be obtained or have items you would like to donate, please contact Dean's Office, School of Pharmacy, 636 West Lombard Street, Baltimore, MD 21201, 301-528-7650.

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Jan. 14-22 — WINTER TRIP TO ST. MAARTEN

Jan. 14 — C.E. Program — Maryland DPS Law — UMBC

Feb. 11 — BMPA Installation Banquet — Blue Crest

Feb. 18 — C.E. Program — Maryland DPS Law – Salisbury

March 4 — Swain Seminar — College Park

March 19 — NARD Legislative Conference, Washington, D.C.

April 5 — MPhA SPRING REGIONAL

April 21-26 — APhA Convention — Anaheim, California

June 24-28 — MPhA CONVENTION — TAMI-MENT, PENNSYLVANIA



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in drug product selection," says Pharmacist Sue Taylor of Yadkinville, N.C. "This is especially true for pharmacists like me

"In making these selections, the pharmacist must have the best information that's available on each product. I think it's an important obligation of drug manufacturers to provide

## We hear you, Sue Taylor

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